HARVARD | BUSINESS | SCHOOL

Who Drives Digital Innovation? Evidence from the U.S. Medical Device Industry

Cirrus Foroughi
Ariel Dora Stern

Working Paper 19-120

Who Drives Digital Innovation? Evidence from the U.S. Medical Device Industry

Cirrus Foroughi
Harvard Business School

Ariel Dora Stern
Harvard Business School

Working Paper 19-120

Who drives digital innovation? Evidence from the U.S. medical device industry

Cirrus Foroughi and Ariel Dora Stern*

April, 2019

Abstract

Does the large-scale technological change that is characteristic of an industry-wide digital transformation entrench industry leaders or enable the rise of new entrants? We offer a novel approach to this question by studying the medical device industry, a unique setting in which we observe all new product commercialization over several years and in which the introduction of software has created fresh opportunities for new product development. Pioneering a new application of text analysis, we consider over 35,000 new medical devices that came to market in the United States from 2002 to 2016 in order to identify digital products. We examine the relative importance of within-firm know-how, geography, and financial resources in predicting digital new product development. We find that prior product-area commercialization experience and location in a region of concentrated expertise reinforce one another as predictors of digital innovation. Access to financing through public capital markets and venture capital are also positive predictors, but the magnitudes of these effects are smaller and do not appear to compensate for past product experience or geography. We conclude that the digital transformation of the medical device industry is disproportionately driven by product area and geographic incumbents.

Keywords: Innovation; Digitization; Medical Technology; Medical Devices; Software

*Harvard Business School, Boston, Massachusetts, 02163 (astern@hbs.edu). We are grateful to Carliss Baldwin, George Ball, Moritz Fischer, Shane Greenstein, Joachim Henkel, Marco Iansiti, Karim Lakhani, Jeffrey Macher, Kyle Myers, Christian Peukert, Scott Stern, and several conference and seminar participants for helpful suggestions. Lynne Chou O'Keefe provided generous insight on the investor's perspective on digital health and Paul Jonak, Lila Kelso, and Melissa Ouellet provided excellent research assistance. The authors are grateful for support from the Harvard Business School Division of Research and Faculty Development and the Kauffman Foundation (Stern).

1 Introduction

In recent years, major industries ranging from manufacturing and inventory management to entertainment to health care have undergone a "digital transformation," in which key aspects of both day-to-day business and new frontiers of product development have migrated to a primarily digital (i.e., software-driven) context. This scenario raises questions about how new opportunities for digital product development impact both new entrants and experienced industry leaders. Does widespread technological change strengthen incumbent power or does it provide greater opportunity for new entry? The answer is not clear *ex ante*: incumbent firms have substantial experiential and resource advantages that could allow them to both weather and take advantage of large-scale technological change, while younger, leaner firms are not burdened by existing research and development (R&D) approaches and are often characterized by creativity and flexibility (Gans and Stern 2003).

This study implements our research question in a novel setting: the digital transformation of the medical device industry. An advantage of this setting is that all product commercialization is directly observable. The existence of a centralized, national regulatory approval process, combined with detailed databases that assign all devices to standardized product areas, allows for precise and comprehensive categorization of new products, which can, in turn, be directly linked to commercializing firms and locations. Using text analysis and document classification techniques, we characterize over 35,000 medical devices brought to market from 2002 to 2016 and identify the digital products among them. We describe the commercialization of these products across medical specialty areas, across types of innovator firms, and over time.

We find that within-firm experience and geographic expertise are the strongest predictors of digital product commercialization. While a firm's previous experience with digital devices is broadly relevant, experience that is specific to a particular medical specialty area (product class) is *additionally* predictive of follow-on innovation (i.e., the commercialization of new versions of already-marketed digital products). This finding points to likely within-firm spillovers from experience in this context. Geography—in particular, a firm's location within a cluster—is a universally strong predictor of digital innovation. Interestingly, this effect is specific to digital experience within

a product class, suggesting that geographic expertise is most relevant for digital innovation when knowledge is specialized. Overall, we find that digital innovation is led by *generalist* firm experts, but is more likely to occur in *specialized* clusters.

With respect to financial resources, we find that access to capital is associated with higher rates of digital innovation, but that these effects are smaller than those associated with experience and geographic expertise. Public firms are more likely to commercialize digital products, but these firms are, by definition, already incumbents. Among newer entrants, our estimates suggest that an order-of-magnitude increase in venture capital (VC) funding would be needed to offset the positive effects of being in a specialized product cluster. Further, the results imply that a doubling of VC funding would be necessary to offset just a single-digit percent increase in a firm's recent experience with related digital devices.

Finally, we observe that different types of access to capital matter in slightly different ways: publicly listed firms are particularly likely to engage in digital innovation of durable medical devices (those used multiple times, often based in hospitals; e.g., ultrasound equipment), whereas VC-funded firms are more likely to pursue digital innovation in single-use devices (those used for only one patient; e.g., pacemakers and insulin pumps). These findings are consistent with stronger inter-temporal spillovers from digital innovation among established firms.

Previous studies have highlighted the importance of software and digitization in determining how firms innovate (Arora et al. 2013; Branstetter et al. 2018) and perform (Brynjolfsson and McElheran 2016). Our study builds in many ways on the literature linking software and networking capabilities to innovative activity; it differs, however, from previous studies, in that our primary measure of innovation goes beyond patenting activity to assess the precise and complete set of new products that are ultimately brought to market. Because new product commercialization in the medical device industry typically occurs well after patenting, this study characterizes software-driven innovation at the tail end of the innovation process, focusing on the final phase of new product development. Furthermore, this study is distinct in that it models digital innovation as a *dependent* variable, whereas other studies have frequently treated the use of software as an independent variable.

We proceed as follows: Section 2 provides background on the U.S. health care industry and on FDA medical device regulation as it relates to the process of new product commercialization. Section 3 presents a conceptual framework for the supply-side cost of new product commercialization, based on firm experience, geography, and financial resources and lays out testable hypotheses. Section 4 describes the data used in the empirical analyses. Section 5 presents estimation results. Section 6 concludes.

2 Background

In the United States, health care spending makes up nearly 18% of the economy (*National Health Expenditure Accounts Highlights* 2016), offering a large potential market for new technologies and a variety of opportunities for innovators to build and grow businesses around new products. A growing segment of the health care market is "digital health," which is broadly defined to include companies and products at the intersection of healthcare and technology.[1] The digital health space includes health care IT and information systems, as well as a host of companies that build and sell technologies such as wireless sensors, software-enabled diagnostic and imaging devices, and artificial intelligence software programs with health care applications. In recent years, there has been dramatic growth in funding for digital health (Tecco and Zweig 2017), with notable private and public initiatives emerging to fund research and investment.[2]

Medical technologies—the devices and equipment used in treating and caring for patients—have become increasingly digitized, as software and networking capabilities have become integrated into a growing number and share of new products. Common examples include digital blood-glucose monitors and nearly all contemporary radiology devices, which combine equipment for imaging with software for image processing and display. Modern medical devices incorporate software for tasks ranging from simple blood pressure monitoring to the processing and analysis of computed

[1] https://rockhealth.com/what-digital-health-is-and-isnt

[2] For example, Rock Health describes itself as "the first venture fund dedicated to digital health" (https://rockhealth.com/about) and the state of Massachusetts launched the Massachusetts Digital Healthcare Initiative in January, 2016 as "a comprehensive public-private partnership that will advise the administration on the future of the Commonwealth's digital healthcare industry" (http://www.mass.gov/governor/press-office/press-releases/fy2017/governor-establishes-mass-digital-healthcare-council.html).

tomography (CT) data. Today, digital medical technology is commonplace and its use is inescapable for health care delivery professionals: a recent report found that U.S. hospitals use an average of 10 to 15 "connected"—i.e., networked—digital devices per patient bed (Newman 2017). Yet until the late 20th century, few software-driven medical devices existed and it wasn't until the late 1990s that the U.S. Food and Drug Administration (FDA) first issued guidance on the incorporation of software into regulated medical devices (FDA, 1999).

While the 21st century has seen rapid digitization of medical data as a result of the growth of electronic health records (Wachter and Howell 2018) and the creation of a multi-billion-dollar digital health investment space (Tecco 2016), the growth of software in medical devices has not yet been characterized across products or firms, nor is it tracked directly by regulators. The implications of digitization for shaping patterns of innovation and commercial leadership in this sector have therefore not yet been studied at scale.

2.1 Regulated Medical Devices

The FDA is the only regulatory authority with the power to grant marketing approval for medical devices in the United States. An agency within the U.S. Department of Health and Human Services, it regulates over two trillion dollars' worth of products annually, including all medical technologies (Babiarz and Pisano 2008). The FDA is organized into centers, each of which focuses on one type of product. Medical devices, including radiation-emitting products such as X-ray and ultrasound machines, are regulated by the Center for Devices and Radiological Health (CDRH).[3] Within the CDRH, the Office of Device Evaluation reviews new products.[4]

Devices are wide-ranging in their complexity and their risk to patients. They range from low-risk devices such as stethoscopes and tongue depressors to moderate-risk products such as hearing aids and blood pressure monitors to complex, high-risk products such as cardiac pacemakers and replacement heart valves. While devices of the lowest risk are subject only to so-called

[3]Other centers are responsible for other product categories. For example, drugs are regulated by the Center for Drug Evaluation and Research (CDER) and biologics are regulated by the Center for Biologics Evaluation and Research (CBER).

[4]Since 1976, the regulation of new medical devices has been governed by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act of 1938.

"general controls" of labeling and of compliance with the FDA's good manufacturing practices,[5] moderate-risk and high-risk devices must submit applications to the FDA for regulatory clearance or regulatory approval, respectively.[6] The administrative data from these regulatory processes, along with each new product's formal description, are made publicly available at the time a device completes regulatory review. These documents constitute the main source of new product data used in our analyses.

As described in detail below, a growing number and share of devices now contain software. Such features allow for additional functionality, such as allowing physicians to remotely diagnose and monitor patients. For example, the CardioMEMS™ HF System allows for remote, wireless heart failure (HF) monitoring, which has been shown to reduce HF hospital admissions for at-risk patients.[7] Despite recognition of the increasingly digital nature of medical devices,[8] the FDA does not formally track the use of software in medical devices in its product-level regulatory data. As a result, the prevalence and growth trajectory of digital products and their distribution across medical specialty areas have not yet been broadly described. The first portion of this paper is therefore dedicated to using information embedded in the text of medical device summaries to identify digital medical devices and quantify their growth. Using text analysis and an off-the-shelf natural language processing tool for medical topic identification, we analyze 15 years of medical device product summaries. We then turn to a set of empirical exercises that model the drivers of digital innovation across firms in this industry.

2.2 Moderate-risk Devices and the 510(k) Process

Moderate-risk devices are approved through a process called premarket notification, which is often referred to as the "510(k) process"—a reference to the section of the law that established this regulatory pathway. One important component of the 510(k) application is the 510(k) Summary, a text document describing the device and published at the time of clearance. The summary includes

[5] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm
[6] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview
[7] https://www.sjm.com/en/sjm/cardiomems
[8] See, for example, the FDA's growing list of guidance documents related to software in medical devices (FDA, 1999; FDA, 2005a; FDA, 2014; FDA, 2016).

"a description of the device such as might be found in the labeling or promotional material for the device" along with "an explanation of how the device functions [and] the scientific concepts that form the basis for the device." The summary also describes "significant physical and performance characteristics of the device, such as device design, material used, and physical properties," making it a clear source of information on the product's key technological characteristics.[9] It is these summaries (and their equivalents for high-risk devices) that are used to construct the text database described below.

A sample 510(k) Summary can be seen in Appendix Exhibit 1. Appendix A provides additional detail on the 510(k) process.

2.3 High-risk Devices and the PMA Process

High-risk (Class III) devices are regulated through a process called Premarket Approval (PMA), which typically requires data from clinical trials in order to establish a device's safety and effectiveness with reasonable certainty.[10] Evidence from trials is presented to the FDA as one part of the PMA package (Kramer et al. 2012).[11]

Like the 510(k) process, the PMA process includes a product-specific summary document, which is made publicly available at the time the device is approved.[12] Much like 510(k) summaries, PMA summary documents contain information on indications for use and a detailed device description—"how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device"—among other components.[13]

Appendix B contains additional detail on the PMA process; a sample PMA summary can be seen in Exhibit 2.

[9] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807

[10] See: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/

[11] Additional details of the PMA review process can be found at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm

[12] These summaries are used along with their moderate-risk device equivalents in the analysis below.

[13] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=814.20

2.4 Software in Medical Devices

The integration of software into medical devices is a relatively recent phenomenon. The first traces of regulatory interest in software in medical devices go back to 1999, when the FDA released its first guidance document, outlining expectations and standards for software embedded in new medical technologies (FDA, 1999). The FDA's guidance has been augmented and updated several times since (e.g. FDA, 2005a; FDA, 2005b; FDA, 2005b; FDA, 2016) and today, medical devices that not only incorporate software but also functionally *rely* on it, are commonplace. Thousands of patients and their physicians have come to depend on software-enabled medical devices, ranging from imaging devices for radiology to software-enabled insulin pumps to implantable heart failure monitors capable of wireless transmission.

2.5 Software in the Health Care Industry

While we are not aware of any studies of the digitization of medical devices, a small but growing body of literature in management and economics explores topics at the intersection of digitization and health care. Most prominently, a number of papers have analyzed the use and adoption of electronic health records (EHRs), one of the primary ways in which software and information technology have impacted health care delivery in the past decade (e.g. Adler-Milstein et al. 2014; Agha 2014; Dranove et al. 2014; Lee et al. 2013; Lin et al. 2018). These studies have documented the ongoing adoption of EHRs along with the heterogeneous (and typically limited or delayed) impacts on patient outcomes.

Our study is also related to a small literature on the adoption and use of software and information technology elsewhere in health care delivery. For example, Athey and Stern (2002) find that basic digitalization of emergency services ("911") increased the short-term survival rate of patients in cardiac distress. Other researchers have considered subtler regulatory factors in health care, such as data privacy laws (Miller and Tucker 2017), in order to understand how new technologies are adopted and used by patients. In the context of telehealth, (Dorsey and Topol 2016) describe the major trends with a particular focus on home and mobile device applications. Yet beyond these studies, management and economics research at the intersection of digitization

and health care is scant and the impacts of digitization on health care innovation have not been rigorously examined.

2.6 Determinants of Innovation

Firm experience and incumbency have been shown to drive innovative activity in contexts ranging from biotechnology Henderson and Cockburn (1996) and pharmaceuticals (Nerkar and Roberts 2004; Morton 1999) to computer and IT hardware (Bayus and Agarwal 2007; King and Tucci 2002). In various settings and competitive environments, research has shown that a firm's experience in an industry is important for predicting when and how it enters new markets. Explanations for the enduring role of incumbent firms are numerous, but include organizational experience in specific types of markets (Morton 1999), productivity spillovers in R&D activities (Henderson and Cockburn 1996), complementarities among technological and product-market experience (Bayus and Agarwal 2007), and experience with the process of new-market entry *itself* (King and Tucci 2002). Using detailed commercialization histories, we are able to revisit the role of firm experience in the context of an industry undergoing digitization.

A number of studies in management and economics have also highlighted the role of geography in innovative activity. Forman et al. (2016) study the competing effects of colocation and coagglomeration of invention, showing evidence of geographic clustering of patents within the San Francisco Bay Area in information and communication technologies as well as more generally. Earlier research from Jaffe et al. (1993) suggests similar dynamics; namely, local knowledge spillovers leading to geographic clustering of patent citations. In the related health care context of biotechnology, Mariani (2004) highlights the role of knowledge spillovers and agglomeration economies in research-intensive sectors.

Finally, firm financial resources are thought to explain firms' innovation activities. Cohen (2010) reviews the literature on this topic and concludes that in many—but not all—settings, cash flow is associated with higher R&D spending, noting that at least for smaller firms, the causality is thought to run from the former to the latter (Hao and Jaffe 1993). In the medical technology setting specifically, data suggest that small firms are particularly capital-constrained and rely on capital

flows from both larger firms and venture capitalists to finance costly new product development (Makower 2010). Thus, our set-up also considers firms' access to capital (in particular, public markets and VC funding) as specific financial resources that may drive innovation.

3 Conceptual Framework

We outline a simple conceptual framework for predicting how firms make decisions to pursue costly new product development projects, given heterogeneity in location, prior experience, and financial resources. In particular, we emphasize that the necessity of a regulatory approval process, along with the accompanying time, financial investments, and institutional know-how required for successful new product development, generate differences in the relative costs of commercialization activities for different types of firms. Our framework focuses solely on the supply-side decision to enter a new market.

A typical feature of digital products is low (or zero) marginal cost of provision to additional customers (Goldfarb et al. 2015), however the cost of developing the digital technology in the first place may be quite large. We build on this intuition, noting that in the case of a multi-purpose technology such as software (for example, for digital data transmission, imaging, or data display), the *marginal* cost of applying the technology to subsequent products within a firm's portfolio will fall as the firm acquires experience. Further, financial resources are known to shape R&D investments at the firm level (Cohen 2010; Hall and Lerner 2010; Kortum and Lerner 2001; and many others). In a setting where multiple factors can influence the cost of new product development, financial resources are another important lever that would be expected to impact the costs associated with digital innovation.

3.1 Framework for firm decision-making

A simple framework for considering firm investments can be seen in the following stylized two-period model: consider a firm, f, from geography g, facing a decision in period 1 ($t = 1$) regarding commercialization of a product in product class s. Commercializing a product involves costs, C_{fstg}, which include manufacturing and production costs, M_{fstg}, and financing costs, I_{fst}, e.g., for product

design and R&D. That is, $C_{fstg} = c(M_{fstg}, I_{fst})$.[14]

Commercialization of a product results in expected revenues in period 2, r_{fst+1}. Firms will invest in commercializing new products when $C_{fstg} < r_{fst+1}$; that is, whenever net expected profits from a given product are positive:[15] $r_{fst+1} - C_{fstg} = \pi_{fstg+1} > 0$.

We consider variation at the firm, product class, time, and geography levels in the empirical models that follow. In the remainder of this section, we leave off subscripts for simplicity.

3.2 Hypotheses

To preview, our conceptual framework predicts that the costs of commercializing a new product will vary with firm know-how, location, and financial inputs to R&D activities. C will therefore be decreasing in E and increasing in I. As a direct corollary, expected revenues in period 2 for firm f commercializing a given device in period 1, π_{t+1}, would be increasing in E and decreasing in I, making firms with more experience, those located in clusters, and/or those with lower financing costs more likely to pursue innovation. In this setup, four assumptions, which are consistent with both the theoretical and empirical literature, are required in order to take into account variation in firm commercialization decisions over time. All cross-partial derivatives of C and π can then be signed, leading to a set of testable hypotheses.

Assumption 1: Manufacturing costs are a function of a firm's labor costs, raw material costs, and prior commercialization experience, such that $M_{ftg} = m(L_{tg}, R_{tg}, E_{ft})$. We assume that all firms can access the same local labor and raw materials markets such that the remaining variation in the cost of manufacturing is only related to differences in know-how, E (that is, prior commercialization experience).

Assumption 2: We can further disaggregate E to allow for both firm- and geography-specific differences in know-how. More precisely, we allow for firm-level and area-level variation

[14] Financing costs may vary by firm and product class and over time, but should not *further* vary by geography after accounting for other factors.

[15] A more detailed model could also account for the relevant discount rate. This stylized 2-period model does not incorporate the fact that it may take more than one period for an investment to realize positive profits, which could also be included in a more detailed model; however, we note that since the average product lifecycle is just 1.5–2 years (Wizemann et al. 2010), it is realistic to assume that products should achieve profitability on a very short time horizon in order to justify commercialization.

in prior commercialization experience such that $E = e(\alpha, \gamma)$, where α is the level of within-firm expertise and γ is the level of local geographic expertise. The importance of within-firm expertise has been extensively documented (Bayus and Agarwal 2007; Henderson and Cockburn 1996; King and Tucci 2002; Nerkar and Roberts 2004; Morton 1999; and many others),[16] as has the role of regional expertise and geography in predicting innovative activity (Delgado et al. 2014; Forman et al. 2016; Mariani 2004; Jaffe et al. 1993; and many others).

Additionally, we note that within-firm and local geographic expertise can be categorized as general or class-specific, such that general experience considers a firm or location's commercialization experience across all software-driven medical devices, while *class-specific* experience considers only a firm or location's software-driven product commercialization experience within a specific FDA product class, such as digital radiology products. That is, E can be divided into general and class-specific components: $E = e(\alpha, \gamma, \alpha_s, \gamma_s)$.

Assumption 3: We expect that class-specific expertise is more transferrable to new product development than expertise outside the focal product class such that class-specific expertise reduces commercialization costs more than general expertise does. Thus, $\frac{\delta E}{\delta \gamma} < \frac{\delta E}{\delta \gamma_s}$ and $\frac{\delta E}{\delta \alpha} < \frac{\delta E}{\delta \alpha_s}$. Our hypotheses then can be stated as follows:

- **Hypothesis 1**: $\frac{\delta C}{\delta E}\frac{\delta E}{\delta \alpha s} < \frac{\delta C}{\delta E}\frac{\delta E}{\delta \alpha} < 0$.
  - **1a:** Within-firm know-how (previous experience) decreases commercialization costs.
  - **1b:** It does so in a way that is increasing in the specificity of within-firm experience.
- **Hypothesis 2**: $\frac{\delta C}{\delta E}\frac{\delta E}{\delta \gamma s} < \frac{\delta C}{\delta E}\frac{\delta E}{\delta \gamma} < 0$.
  - **2a:** Local geographic expertise (being located within a cluster) decreases commercialization costs.
  - **2b:** It does so in a way that is increasing in the specificity of local expertise.

Assumption 4: We assume that a firm's financing cost, I, is correlated with its access to external capital, through either public capital markets or venture capital financing. This is

[16] This is also consistent with the theory of economies of scope as described by Panzar and Willig (1981) and as seen in empirical studies such as Henderson and Cockburn (1996).

consistent with literature linking firm performance and innovation to access to finance and financial constraints (Cohen 2010; Cohen and Klepper 1996; Hao and Jaffe 1993; Stern 2017). We can therefore write I as a decreasing function of (a) being publicly listed (having access to public capital markets), ϕ and (b) being VC-funded, v. We can then define I as a function i, where $I = i(\phi, v)$ and $\frac{\delta I}{\delta \phi}$ and $\frac{\delta I}{\delta v}$ <0.

The next set of hypotheses therefore address the implications of financial resources on expected patterns of commercialization, in which smaller and more capital-constrained firms will face higher costs of pursuing digital innovation:

- **Hypothesis 3**: $\frac{\delta C}{\delta I}\frac{\delta I}{\delta \phi} < 0$. The cost of digital new-product development will be lower for publicly listed companies, making them more likely to commercialize new products.
- **Hypothesis 4**: $\frac{\delta C}{\delta I}\frac{\delta I}{\delta v} < 0$. The cost of digital new-product development will be lower for firms with venture capital funding, making them more likely to commercialize new products.

Importantly, we expect these dynamics to emerge as novel manifestations of firm advantage in digital new product commercialization. That is, the digital-product-specific components of firm experience, geography, and access to financing should matter *above and beyond* the advantages that these factors may confer already, when considering firms' commercialization patterns more broadly. We test each of these hypotheses in the analyses described below.

4 Data, Classification, and Summary Statistics

4.1 Summary

This project draws on four main sources of data. We begin with administrative data on all FDA-regulated moderate-risk and high-risk medical devices that came to market over 15 recent calendar years; namely 2002 to 2016, inclusive. For each device, we collect and analyze the text of the accompanying product summary or statement.

Using an automated script and two different types of supervised document classification, we identify and characterize digital (software-driven) devices. First, we document the incidence and

frequency of keywords related to software and networking capabilities in products and track these keywords over time. Subsequently, we use the National Library of Medicine's Medical Text Indexer (MTI)[17]—a set of document classification algorithms that take free text and provide subject indexing recommendations based on the Medical Subject Headings ("MeSH®" vocabulary) established by the National Institutes of Health (NIH)—to validate the keyword-driven classification exercise. Using the commercializing firm's identity along with historical data about the location of a given product application and firm-level financial data, we characterize commercializing firms at the time each medical device in our dataset came to market.

4.2 Administrative Data on New Medical Devices

The first dataset for this project comes from combined regulatory clearance documents associated with all new moderate-risk and high-risk medical devices that came to market in the United States after 1996. Moderate-risk devices—such as hearing aids, blood pressure monitors and echocardiograph devices—are the largest category of devices regulated by the FDA, while high-risk devices—such as pacemakers and drug eluting stents—make up a smaller share of new products. Moderate-risk device clearance happens through a process called "510(k)," while high-risk device approval occurs through the PMA process. Both processes are described briefly above (Section 2) and in detail in Appendices A and B, respectively. These processes are the final step of the research and development process, after which a cleared/approved product can be legally marketed in the United States. The FDA has historically received approximately 4,000 applications for new 510(k) devices annually, compared to fewer than 100 PMA applications (Maisel 2004).

The FDA's 510(k) clearance database[18] and PMA approval database[19] include the full set of device names, product codes (three-letter classifications that categorize devices according to site of use and purpose), and submission and FDA decision dates for all products cleared/approved for marketing. The top eight medical specialty areas (classes) account for over 75% of all new product approvals and are the focus of this study (Table 1). For each of these classes, there were over 2,000

[17] https://ii.nlm.nih.gov/MTI
[18] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
[19] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm

unique new device approvals between January 1, 2002 and December 31, 2016.[20] Due to availability of product descriptions (as described below) this is our period of analysis. Over this period, 35,794 new regulated devices came to market in the United States. Each class of devices includes multiple product codes and (typically) multiple unique devices within each product code. Figure 1 presents a simple example of the hierarchy of the classification system.

4.3 Rich Text Data

The second data source is a novel database of text files made up of the device summaries (standardized product descriptions). At the time of 510(k) clearance or PMA approval, a "summary" or "statement" is published for each device. As noted above, the summary must contain "a description of the device...including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics" (such as design and physical properties).[21] In less than 10% of cases in our sample years, a related document called a "statement" was published in lieu of a summary,[22] in which case, we used the text from the statement instead. While somewhat less detailed than summaries, statements also contain relevant information about the content of products (for example, several included use of the word "software") and therefore provide the type of text information that is relevant for product classification in this study.[23] We hereafter use the term "summary" broadly to refer to both types of document.

Device summaries are published as online PDF documents following a standardized URL-format and we use an automated script to batch download all posted documents. These documents began to be digitized in May 2001 and we begin our study sample in 2002, the first full calendar year with digitized summaries available. Using Abbyy FineReader optical character recognition

[20] These eight classes are defined using the full set of FDA clearance records available and therefore represent the universe of newly approved, FDA-regulated devices.

[21] https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm; as noted above, Exhibits 1 and 2 present examples of 510(k) and PMA summaries, respectively.

[22] https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm089452.htm

[23] In theory, the use of statements could lead to under counting digital products if their text files are less detailed. Therefore, in robustness tests (unreported), we confirm that all results hold when considering the sample of product summary documents only.

(OCR) software, we convert downloaded documents into machine-readable text files. In total, ninety-eight percent of the product summaries could be converted to a machine-readable format giving us 35,794 device-text pairs.[24] We have no systematic concerns regarding selection or time trends in missing text data: the machine-readability of online PDFs is not statistically different across medical specialties overall, in any year, or over time. For all years, at least 97% of all digital documents were machine-readable following OCR document processing. Appendix C, Table I presents the number of machine-readable summaries in our sample by calendar year.

Although the use of text-based data—for example, categorizing phrases to document firm extensions into new products and services, as in Greenstein (2000)—has a well-established history in empirical analysis, the automation of these exercises is a relatively nascent phenomenon. Gentzkow et al. (2017) describe several techniques for parsing and analyzing text data and highlight the fact that "the information encoded in text is a rich complement to the more structured kinds of data traditionally used in research." In recent years, text data has been used in studies ranging from sentiment analysis of policy uncertainty (Baker et al. 2016) to labor economics (Deming and Kahn 2018) and in the analysis of patent data (Moser et al. 2017). Here, we demonstrate the utility of automated classification of product types at scale for understanding the content and functionality of new medical devices.

We process text files in two ways, each of which leads to a similar classification of digital medical devices. Our first approach is a form of supervised document classification in which we identify the incidence and frequency of keywords related to software and networking capabilities in each device description. These terms were selected in advance using two online glossaries of computer-related terms.[25] (A list of the 36 most frequently used keywords—each of which were found in over 100 unique product descriptions—can be found in Table II of Appendix C.) Unsurprisingly, the use of "software" and several related keywords has increased over time (Appendix C, Figure I). Because "software" is the most common among our search terms and is highly correlated with others, we rely on its inclusion in a product's description as our first indicator to identify digital products.

[24] These include 35,495 510(k) summaries and 299 PMA summaries.

[25] Composite list from http://www.math.utah.edu/∼wisnia/glossary.html and https://pc.net/glossary

Categorizing products by keyword use is our first application of simple document classification to identify digital devices. It has the advantage of being simple and highly transparent, but the disadvantage of being somewhat *ad hoc*. However, this method is very successful in identifying products of interest. In particular, since the product descriptions included in FDA clearance documents are standardized and parsimonious, there is no reason—and indeed no option—to include extraneous text related to features that are not included in the device itself. To put it simply, keywords such as "software" will not appear in the product description if they do not relate to aspects of the device's functionality (see Appendix Exhibits 1 and 2). Nevertheless, we performed several manual inspections to confirm that incidents of keywords found were indeed references to the technology in the device: we drew a random sample of 120 devices (eight per calendar year) that had been flagged for including "software" and manually inspected each of these devices' summaries. In this sample, 100% of devices flagged as including "software" were found to be correctly coded (that is, a 0% rate of type I error in this random subsample).

We validate our *ad hoc* supervised document classification using the National Library of Medicine's MTI algorithm. As noted above, the MTI takes free text as an input to provide subject indexing recommendations based on the MeSH vocabulary established by the NIH. Since our primary measure of digitization is the incorporation of software into new products, we classify device descriptions using the MTI and generate an indicator for whether the algorithm assigned the MeSH code for *software* to the product.[26] The MeSH code for "software" broadly covers "sequential operating programs and data which instruct the functioning of a digital computer," a slightly higher bar for classifying digital products than searching for the keyword "software" alone.

The MTI algorithm has the advantage of having been externally validated by the NIH and by several years of use by the National Library of Medicine, but has two clear disadvantages. First, as noted above, we believe that the bar may be higher for flagging product descriptions for software inclusion (that is, identifying digital devices), since the MTI will require a *discussion* of software programs in the text, beyond simply using the keyword "software." For this reason, our expectation is that the MTI may identify a more software-intensive subset of products in our

[26] In the MeSH tree, "software" takes the tree number L01.224.900. We identify all products that are classified as being anywhere on the "software" branch of the MeSH tree.

sample. Second, the MTI is non transparent in how it assigns concepts to text, since the algorithm itself has not been published.[27]

Comparing the MTI output to our own keyword-based document classification method, we find high degree of overlap: 100% of the devices flagged by the MTI as describing software are also identified by the keyword method as being about software. However, as expected, not all summaries using the keyword "software" are identified by the MTI. The rightmost column of Table II in Appendix C presents a cross-tabulation of our *ad hoc* keyword-based document classification versus the MTI's classification. Notably, the actual keyword "software" has the highest degree of overlap with the MTI-based definition.

Because we care primarily about digitization in the sense of incorporating *any* software, we focus on the keyword-based definition for our primary analysis; however, for all regression models, we test the alternative (MTI-based) definition and present alternative versions of all key tables in Appendix C. The choice of definition does not appear to change the sign or statistical significance of the main results below, but magnitudes are attenuated roughly proportionally to the decrease in the number of software devices included in the MTI-defined sample.

Figure 2 presents the growth of new digital devices over our observation period. Figure 3a shows the growth in digitized product codes—unique *types* of devices—over time, while Figure 3b shows growth in the number of *firms* pursuing digital innovation. Through these figures, we see that the growth in digital devices has been a result of the entry of both new products and new firms. Figure 4a shows that the number of digital product codes grew by over 400% over this period, while non-software product codes grew by only about 150% (albeit off a higher baseline). Figure 4b breaks down the growth of digital devices across medical specialty classes, revealing interesting heterogeneities. Although all classes show growth in digital products, the share of new products that are digital varies dramatically across medical specialty classes.

[27]The MTI algorithm is not directly observable/open source; we batch-process text files through the algorithm and record the subject headings that the MTI returns as output.

4.4 Measuring Firm Experience and Geographic Clusters

We characterize firms' digital device experience along two dimensions. First we calculate the count of digital devices the firm commercialized in the three years *prior* to the year of observation. This window is consistent with the medical device development period, which may run over two years (Wizemann et al. 2010). Second, we calculate the count of digital devices within each *class* that the firm commercialized over the same three-year window of time (up to, but not including, the year of observation). We calculate total (digital and non-digital) devices commercialized by each firm in the same manner to be used as measures of overall firm experience.[28]

With respect to geography, we characterize firms as to whether or not they are in a "digital cluster" in three (increasingly specific) ways.[29] Each of these definitions requires limiting the sample to U.S.-based applications in order to operationalize a consistent definition of state-based geographic clusters. Notably, many of these applications are from U.S. offices of firms headquartered outside of the United States, so many large, international firms are in the final sample.

First, we consider local labor market expertise. Using annual data for 2016 from the U.S. Bureau of Labor Statistics (BLS), we compile data on each state's share of software engineers in the labor force[30] in order to consider whether there is a relationship between the characteristics of the skilled IT workforce in a state and the likelihood of digital innovation emerging from that state. Because each application includes an address, we can see the location of the facility from which a device application was submitted. Appendix Figure II presents a set of sample states. While there is some variation over time within states, the primary source of variation in the share of software engineers is across states.

Next we consider two types of state cluster for digital innovation, as defined by where device commercialization took place in preceding years. We define digital clusters by identifying the top 20% of states for digital device commercialization, based on a three-year moving average of the number of digital products brought to market in the period leading up to the year of observation.

[28] in robustness tests, we also consider a two-year and a five-year window of past firm experience

[29] We also define overall device commercialization clusters in analogous ways to be used as controlls.

[30] Data were available for 2005 to 2015 inclusive; however, our analysis sample spans 2005 to 2016. In order to estimate 2016 data, we impute 2016 state employee shares based on a linear projection from the prior five years, which is similar to the method that BLS uses in its own projections.

We then consider a class-specific version of this definition, in which we define the top 20% of states for digital device commercialization within each product class. Based on each of these definitions, we create an indicator variable for whether or not a device originated from a cluster. The sample used in regression analysis is limited to the years 2005 to 2016 (inclusive), to facilitate a three-year look-back on regional product expertise. For example, a data point in the year 2005 uses data from the years 2002, 2003, and 2004. Using these two definitions, Appendix Figures III and IV show the share of digital devices originating from clusters versus those not originating from clusters.

By using a three-year look-back to define clusters and to define firms' digital device experience, our analysis sample includes only the set of products that came to market in the years 2005-2016 (although data from the years 2002 to 2004 are used to define important firm measures in the early years of the analysis sample). Further, we limit our analysis sample products commercialized in the United States (including those commercialized by foreign firms with U.S. regulatory submission addresses), in order to tractably and consistently define geographic clusters. The final analysis sample includes 22,291 observations at the product level (Table 1). Table 2 presents summary statistics of all variables used in regression models.

4.5 Firm Financial Data

Each device is linked by its commercializing entity to detailed firm financing data. We first link commercializing entities to a panel of firm acquisitions created using data from *EvaluateMedTech*[31] in order to account for subsidiary ownership and introduce the notion of *child* (acquired) and *parent* (acquirer) firms. These child and parent firms are then separately linked to data on each firm's public listing status and venture capital data. In order to link firm-level datasets, we use the software program *matchIT*, which performs fuzzy matching of company names (or addresses) between (or within) datasets and grades the text match quality by score. We used this software because it is highly flexible, fully parameterized, and deals effectively with foreign names. Firm names were cleaned using a consistent set of rules to account for suffixes and abbreviations.[32]

Data on venture capital funding are assembled from *EvaluateMedTech* and *Preqin*, with

[31] A market intelligence database that tracks public and private firms in the medical device industry.
[32] This method is similar in nature to work done for the NBER Patent Data Project by Bessen.

precedence given to the latter.[33] We observe deal dates and funding amounts for each linked firm, which we use in creating (a) lagged binary indicators for whether a firm was ever venture-funded or venture-funded prior to product commercialization and (b) running totals for dollar values of venture funding.

Data on firm public listing were collected from *EvaluateMedTech* and *Capital IQ*, with precedence given to the former, as it has broad coverage of the medical device industry.[34] These data allow us to create a binary indicator for whether the commercializing firm was publicly listed at the time a given product came to market. Appendix Figures V and VI show the share of digital devices that were commercialized by venture-capital–funded firms (in the sample of all privately-held firms) and by public firms, respectively.

5 Estimation and Results

In the estimation exercises that follow, we test the hypotheses outlined in Section 3.2. First, we explore evidence for Hypotheses 1 (firm experience) and 2 (geographic clusters) and the likelihood of a firm engaging in digital device innovation. Next, we explore evidence for Hypotheses 3 and 4 by modeling the relationship between firm financial resources (public capital and VC funding, respectively) and digital innovation. In combined models, we consider all factors simultaneously and explore mechanisms.

5.1 Overall Estimates

Trends in digital innovation in medical technology and the observed variation across medical specialty classes can be seen in Figures 2 to 4. Notably, there is significant heterogeneity across classes in the volume (Figure 2) and share (Figure 4b) of digital innovation. There are also clear time trends, with the number of new digital products growing over time. Among other things, the descriptive findings point to the importance of using product class and year controls in empirical

[33] Preqin is widely considered the best publicly available dataset for venture funding and has been used in a variety of recent studies (e.g. Harris et al. 2014 and Korteweg and Nagel 2016).

[34] We validate *EvaluateMedTech* data using *Capital IQ*, long considered a primary source for detailed firm financials. See, for example, Acharya and Xu (2017); Booth and Salehizadeh (2011); Sheen (2014).

models. We model the likelihood of digital innovation, D, as:

$$D_{fpct} = f(\beta \mathbf{X}) + \epsilon,$$

where the regressors include:

- Indicators of expertise (within-firm experience and geographic), each of which can be general or class-specific.
- Indicators of firm financial resources, including whether a product emerged from a publicly listed firm or a VC-funded firm.
- Controls for:
  - Clearance year, in order to capture time trends in software inclusion over time.
  - Medical specialty class, in order to account for persistent differences in the relative ease or applicability of software in a given area of medicine and medical technology.
  - The firm's overall level of recent device innovation (that is, all product commercialization), such that any additional statistical relationships identified represent *additional* effects seen for digital devices.
  - The firm's location in a general device cluster (that is, all devices, not just digital products), such that any additional statistical relationships identified represent *additional* effects seen for digital devices.
- An error term, ϵ.

In the regression models below, all specifications include controls for the focal firm's volume of recent commercialization activity, controls for the locations of general medical device clusters, and year and class fixed effects, with standard errors clustered at the product-code level in acknowledgement of potential differences across product type (for example, as a result of differences in innovation behavior or regulatory burden). All tables report marginal effects from logit models,

facilitating a more direct interpretation of statistical relationships.[35]

Table 3 presents a full set of controls. As expected, there are statistically significant differences across classes and over time. For example, all else equal, radiology devices are over 61 percentage points more likely to be digital than orthopedic devices (the omitted category), while the time trend indicates that, all else equal, the likelihood of a new device being digital increases by roughly 1.3 percentage points with each passing year. Column 1 uses year fixed effects, while Column 2 includes a time trend. Notably, the coefficients on the class controls are very similar across the two samples. The pseudo-R-squared values are trivially higher in the models using year fixed effects rather than a time trend, so we use the full specification in Column 1 as controls in all subsequent regressions (however, results are stable regardless of the convention chosen for including this set of control variables).

5.2 Geographic and Within-firm Know-how

Table 4 presents results predicting digital innovation at the product level, specifically evaluating Hypotheses 1 and 2.

Columns 1 to 3 consider the role of within-firm experience in predicting digital innovation. Column 1 shows a strong, statistically significant relationship between general digital device experience and the current likelihood of digital innovation. Relative to the sample mean, a one-standard-deviation increase in general firm experience is associated with a 33% increase in the likelihood of commercializing a digital product.[36] Column 2 shows a class-specific relationship between firm experience and the current likelihood of digital innovation. Relative to the sample mean, a one-standard-deviation increase in class-specific firm experience is associated with a nearly 37% increase in the likelihood of commercializing a digital product. Column 3 indicates some attenuation of the effect sizes seen in Columns 1 and 2 for the obvious reason that class-specific experience is a subset of general experience; however, the effects are individually and jointly highly significant and suggest large magnitudes for the relationship between a firm's recent experience in

[35] A full set of corresponding linear probability models (excluded due to length and redundancy) lead to the same conclusions as those presented below.

[36] Natural logarithms of the values presented in Table 2 were used for this and the following calculations.

digital product commercialization and its current likelihood of digital innovation.[37]

Columns 4 to 7 consider the role of geography in predicting digital innovation. We find that although a state's share of software engineers (Column 4) is not a statistically significant predictor of digital innovation (although the coefficient is positive, as expected), other measures of geographic expertise are associated with a much higher likelihood of digital innovation. Dummy variable indicators for being in either a general digital device cluster (Column 5) or being in a class-specific digital device cluster (Column 6) are both strongly associated–both individually and jointly–with higher probabilities of digital innovation in new products (Column 7). In the combined model, which suffers least from potential omitted-variable bias, we observe that being in a general digital device cluster is associated with a 4.1 percentage point increase in the likelihood of digital innovation, while being in a class-specific cluster increases that probability by a further 13.3 percentage points.[38] Further, these magnitudes are large: devices in the sample were roughly 30% digital in 2016, the final year of observation. This implies that being located in a general digital device cluster would (conservatively) increase the baseline likelihood of digital innovation by 13.7% while being in a class-specific cluster would increase it by over 44%.[39]

Column 8 of Table 4 presents an "all-in" model that combines both experience and geography. The magnitudes of the coefficients are similar to those in Columns 3 and 7, with the exception of general digital device clusters becoming an insignificant predictor of digital innovation. Column 8 therefore suggests that after controlling for factors related to firm experience, only location in a class-specific cluster is additionally predictive of digital innovation. The similarity of the remaining coefficients across specifications in Table 4 indicates that within-firm experience and class-specific geographic expertise are mostly independent of one another and have largely orthogonal impacts in these predictive models. The findings in Table 4 support Hypotheses 1a, 1b, and 2b and partially

[37]These findings are also consistent with the experience of a former medical device industry executive who was interviewed about these findings *ex post*. He described a relatively siloed R&D process within the companies he was most familiar with, where knowledge was likely to spill over first within business units. Medical device firms' business units tend to be organized by medical specialty area (e.g., interventional cardiology) and such specialties largely correspond to the classes used here. The class-specific nature of the spillovers documented in Table 4 were described by the executive as "unsurprising."

[38]In this model, the state's share of software engineers is also predictive of digital innovation.

[39]Being in a digital device cluster is associated with a 4.1 percentage point increase in the likelihood of digital innovation off a mean of 30%, for a 13.7% increase. A similar calculation was done to arrive at the 44% figure for being in a class-specific cluster.

support Hypothesis 2a.

5.3 Firm Financial Resources

Table 5 presents results from regressions designed to evaluate Hypotheses 3 and 4. We first consider whether public firms (Column 1) and VC-funded private firms (Column 2) are more likely to engage in digital innovation. We find that VC funding is on its own a statistically significant predictor of digital innovation, with VC-funded firms roughly 3 percentage points more likely to innovate digitally, all else equal. Column 3 presents results when using the natural logarithm of the cumulative dollar value of VC funding up to the year of commercialization as a predictor. These results indicate that a one-standard-deviation increase in a firm's VC funding is associated with a 4.1 percentage point higher likelihood of digital innovation. [40] Columns 4 and 5 present results from combined regression models that consider public status and VC funding (or funding amounts) simultaneously, finding again that only venture-capital–funding indicators (both as a binary status and as a cumulative funding total) are statistically significant predictors of new digital commercialization. Column 6 presents the same model as Column 5, but uses the full set of firm experience and product cluster controls used in Table 4; results are unchanged.

Based on Table 6 alone, only Hypothesis 4 is broadly supported by the data. However, we note that if either measure of firm financing is correlated with omitted variables, such as geography, the models in Table 5 will suffer from omitted-variable bias. Therefore, in the next set of regressions, we explore fully specified models.

5.4 Further Regression Analysis and Mechanisms

Table 6 presents a set of combined models in which Hypotheses 1 to 4 are evaluated simultaneously, with further *post-hoc* extensions to consider drivers of novel versus follow-on innovation and to consider potential differences between durable versus single-use devices.

Column 1 presents an all-in predictive model using the entire regression sample. Differences between the results presented in Column 1 of Table 6 and those seen in Tables 4 and 5

[40] This calculation uses the natural logarithms of values presented in Table 2.

therefore indicate the size and direction of any omitted-variable bias that may have been unintentionally introduced by assessing individual hypotheses separately. We find that the main difference in this all-in analysis is that being a publicly listed firm is now associated with a higher likelihood of digital innovation, thus providing conditional support for Hypothesis 3.

In these specifications, access to capital is associated with more digital innovation; however, these effects are smaller than those associated with experience and geographic expertise. After controlling for other factors, public firms are more likely to commercialize digital products by roughly four percentage points (Column 1), but these firms are, by definition, already incumbents. Among new entrants, VC continues to be a positive (albeit less powerful) predictor of digital innovation. Back-of-the envelope calculations suggest that a firm would need an exponential increase in its VC funding in order to compensate for the benefit afforded by simply being located in a specialized product cluster. Alternatively, the results imply that a doubling of VC funding would be necessary in order to offset just an 8.5% increase in a firm's recent class-specific experience with other digital products–the equivalent of roughly one additional digital device's worth of recent commercialization experience.

In additional *post-hoc* analysis presented here, we split the sample into novel digital devices (first-of-their-kind) and follow-on digital devices (new versions of already-marketed digital products), as in Columns 2 and 3. We see only one major difference between these two types of digital product commercialization: the importance of class-specific experience in the overall analysis appears to be driven by its role in predicting follow-on innovations. In other words, first-of-their-kind innovations are less reliant on specialized within-firm experience than follow-on innovations, a result that is intuitive and, in part, mechanical. The fact that product-class–specific experience predicts follow-on innovation strongly points to likely within-firm spillovers from experience in this context and is consistent with notions of information friction (Teece 1982) and asset complementarity (Teece 1986).

In a final *post-hoc* analysis, we observe that different types of access to capital matter in slightly different ways for considering durable medical devices (those used multiple times and often based in hospitals, such as ultrasound equipment) versus single-use medical devices (those used in

only one patient, such as pacemakers or insulin pumps). Columns 5 and 6 indicate that publicly listed firms are over five percentage points more likely to engage in digital innovation of durable devices, whereas VC-funded firms are more likely to pursue digital innovation in single-use devices.[41] These findings are consistent with stronger intertemporal spillovers from digital innovation among established firms. Class-specific experience is also a stronger predictor of single-use versus durable digital devices. This may indicate that class-specific learnings and spillovers are less important for durable medical equipment, where general purpose digital components such as digital monitors or digital data storage are more likely to be relevant.

5.5 Robustness Tests and Alternative Specifications

We also undertake a series of exercises as robustness tests of our main findings. The primary analysis presents results using geographic and within-firm expertise variables constructed using three-year look-backs; this was chosen as a result of the natural 2+ year product development cycle for medical devices discussed above. However, we also estimate all models using versions of these measures constructed based on two-year and five-year look-backs. For brevity, we do not report coefficients, although all of our findings remain highly similar using those alternate constructions of experience.

Second, we consider our alternative form of document classification for the identification of digital medical devices in order to verify the results generated using our supervised, keyword-based classification method. As discussed in Section 4, we use the National Library of Medicine's Medical Text Indexer (MTI) algorithm to identify medical devices whose product statements or summaries are flagged as discussing software. Tables 4, 5, and 6 of Appendix C present MTI-based analogues of our keyword-based results in Tables 4, 5, and 6 in this paper. We find that all of our main results are robust to this different classification method, with magnitudes only somewhat attenuated due to the potentially more conservative nature of the MTI algorithm.

[41] Column 4 presents results from the same statistical model as used in Column 1, but on a limited sample that excludes "clinical chemistry" devices, which, for technical reasons, could not be easily classified into durable versus single-use products and were therefore excluded from the analysis in Columns 5 and 6.

6 Discussion and Conclusions

In this study, we describe the digital transformation of the medical device industry and consider how new opportunities for digital product development have been pursued by both new entrants and incumbents. In this setting, we observe all new product commercialization over a 15-year period and document several trends in the digitization of medical technology and their implications for the industry.

We first characterize the growth of digital products over time and across medical specialties, finding important differences. For example, by 2016, there were over twice as many digitized product types and more than three times as many new digital product approvals for cardiovascular devices than for orthopedic devices. These descriptive findings are novel; to our knowledge, no other studies have comprehensively characterized the digitization of products in this industry. Further, we develop and validate a method for using supervised document classification to analyze the contents of product descriptions. We use multiple methods to collect indicators of the use of software in product descriptions of new medical devices and cross-validate our findings.

We then turn to unpacking the factors that predict which firms drive digital innovation in this setting and find several pieces of evidence that point to significant incumbent advantages. We observe a strong relationship in which both geographic digital product clusters and prior digital product commercialization experience–above and beyond existing *general* clusters and *overall* new product commercialization experience–predict digital innovation. Class-specific firm experience is even more strongly associated with digital innovation, pointing to the importance of product area experience when commercializing new digital devices.

The importance of firm experience is evocative of other studies of the medical device industry, such as Chatterji (2009), that emphasize the importance of regulatory knowledge, marketing knowledge, and understanding of market opportunities in the medical device industry. The results are also similar to those seen in other settings, where the important role of "complementary know-how" in a changing industry has been well documented (Helfat 1997). More broadly, our findings are consistent with the evidence that acquired know-how has positive spillovers not only within firms, but also across firms in a local labor market, as summarized by Azoulay and Lerner (2012).

Interestingly, within-firm experience and class-specific geographic expertise are mostly independent of one another and have largely orthogonal impacts in these predictive models. This suggests that being advantageously located can compensate to some extent for lack of within-firm know-how (and vice versa).

We also consider how access to capital may support digital innovation and we find positive–but comparatively small–effects of financial resources on predicting digital innovation. After controlling for other factors, public firms are more likely to commercialize digital products, as are those with VC funding, however we find that in order to have a comparable likelihood of commercializing a digital device, a firm would need orders of magnitude more VC funding in order to compensate for the benefits of being in a specialized product cluster. Considering differences between novel versus follow-on innovations, we find that first-of-their-kind digital products appear to be less reliant on within-firm experience than are follow-on innovations, for which there appear to be stronger spillovers from medical-specialty-class–specific activities. Finally, we observe that, in this setting, publicly listed firms are more likely to commercialize durable medical devices, which are used over longer periods of time and are often hospital-based, relative to privately-held and/or VC-funded firms, which are more likely to pursue single-use products. These findings support stronger intertemporal spillovers from digital innovation among established firms.

Taken together, our results suggest that industry incumbents–by multiple definitions–are driving digital innovation in the U.S. medical device industry. We observe within-firm and within-cluster spillovers from past digital innovation into future digital innovation as well as a positive role of large, publicly listed firms (which are, by definition, established players). Venture capital funding does appear to play a small role in supporting digital innovation, but this role is dwarfed by that by other factors. We conclude that in this industry setting, where the costs of entering new product markets are high, digital innovation favors firms with an incumbent advantage.

An important caveat to this study is that we have characterized just one industry. Our setting is advantageous because data on all new product commercialization can be observed and databases are detailed and provide rich product detail. However, it is a setting in which entry barriers shape the relatively high costs associated with entering new product markets. We therefore

expect that our findings are most likely to be relevant in other settings–whether regulated industries or not–in which the cost of entering a new product market is non trivial and where supply-side costs are therefore relevant predictors of new market entry behavior.

These findings have important managerial and policy implications. For firms considering digital market entry, our results suggest that in settings with significant entry costs, incumbent firms are likely to play a more significant role in digital product development than new entrants. More specifically, firms with digital product experience are at an advantage relative to firms with only general product experience. However, the geographic concentration of digital new product development in specific product areas points to advantages for *both* new entrants and incumbent firms located in these clusters. As noted above, these effects appear to be largely orthogonal: being advantageously located can to some extent compensate for a lack of digital product experience, and contrariwise. Thus, new entrants may strategically benefit from co-locating with early digital leaders in their industry.

For policy-makers, our findings suggest the importance of prior experience when undertaking digital product commercialization. To the extent that policy-makers want to support new entrants, clear guidance on best practices for developing digital products may serve as a substitute for prior experience. As regulators increasingly devote attention to clarifying expectations for digital devices–for example, through the FDA's new "digital health software pre-certification" program,[42] which allows a small group of technology leaders to commercialize new software products more efficiently–it will be important to keep such considerations in mind.

References

Acharya, Viral and Zhaoxia Xu, "Financial dependence and innovation: The case of public versus private firms," *Journal of Financial Economics*, 2017, *124* (2), 223 – 243.

Adler-Milstein, Julia, Joseph Kvedar, and David W Bates, "Telehealth among US hospitals: several factors, including state reimbursement and licensure policies, influence adoption,"

[42] https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm

Health Affairs, 2014, *33* (2), 207–215.

Agha, Leila, "The effects of health information technology on the costs and quality of medical care," *Journal of Health Economics*, 2014, *34*, 19 – 30.

Arora, Ashish, Lee G Branstetter, and Matej Drev, "Going soft: How the rise of software-based innovation led to the decline of Japan's IT industry and the resurgence of Silicon Valley," *Review of Economics and Statistics*, 2013, *95* (3), 757–775.

Athey, Susan and Scott Stern, "The Impact of Information Technology on Emergency Health Care Outcomes," *The RAND Journal of Economics*, 2002, *33* (3), 399–432.

Azoulay, Pierre and Josh Lerner, "Technological Innovation and Organizations," in Robert Gibbons and John Roberts, eds., *The Handbook of Organizational Economics*, Princeton University Press, 2012.

Babiarz, Josephine C and Douglas J Pisano, "Overview of FDA and drug development," in "FDA Regulatory Affairs," CRC Press, 2008, pp. 11–42.

Baker, Scott R, Nicholas Bloom, and Steven J Davis, "Measuring economic policy uncertainty," *The Quarterly Journal of Economics*, 2016, *131* (4), 1593–1636.

Bayus, Barry L and Rajshree Agarwal, "The role of pre-entry experience, entry timing, and product technology strategies in explaining firm survival," *Management Science*, 2007, *53* (12), 1887–1902.

Booth, Bruce L and Bijan Salehizadeh, "In defense of life sciences venture investing," *Nature Biotechnology*, 07 2011, *29*, 579 EP –.

Branstetter, Lee G, Matej Drev, and Namho Kwon, "Get with the program: Software-driven innovation in traditional manufacturing," *Management Science*, 2018.

Brynjolfsson, Erik and Kristina McElheran, "The rapid adoption of data-driven decision-making," *American Economic Review*, 2016, *106* (5), 133–39.

Chatterji, Aaron K, "Spawned with a silver spoon? Entrepreneurial performance and innovation in the medical device industry," *Strategic Management Journal*, 2009, *30* (2), 185–206.

Cohen, Wesley M., "Chapter 4 - Fifty Years of Empirical Studies of Innovative Activity and Performance," in Bronwyn H. Hall and Nathan Rosenberg, eds., *Handbook of The Economics of Innovation, Vol. 1*, Vol. 1 of *Handbook of the Economics of Innovation*, North-Holland, 2010, pp. 129 – 213.

_ **and Steven Klepper**, "A Reprise of Size and R&D," *The Economic Journal*, 1996, *106* (437), 925–951.

Delgado, Mercedes, Michael E Porter, and Scott Stern, "Clusters, convergence, and economic performance," *Research Policy*, 2014, *43* (10), 1785–1799.

Deming, David and Lisa B Kahn, "Skill requirements across firms and labor markets: Evidence from job postings for professionals," *Journal of Labor Economics*, 2018, *36* (S1), S337–S369.

Dorsey, E Ray and Eric J Topol, "State of Telehealth," *New England Journal of m=Medicine*, 2016, *375* (2), 154–161.

Dranove, David, Chris Forman, Avi Goldfarb, and Shane Greenstein, "The trillion dollar conundrum: Complementarities and health information technology," *American Economic Journal: Economic Policy*, 2014, *6* (4), 239–70.

Forman, Chris, Avi Goldfarb, and Shane Greenstein, "Agglomeration of Invention in the Bay Area: Not Just ICT," *American Economic Review*, May 2016, *106* (5), 146–51.

Gans, Joshua S and Scott Stern, "The product market and the market for "ideas": commercialization strategies for technology entrepreneurs," *Research Policy*, 2003, *32* (2), 333–350.

Gentzkow, Matthew, Bryan T Kelly, and Matt Taddy, "Text as Data," Working Paper 23276, National Bureau of Economic Research March 2017.

Goldfarb, Avi, Shane M Greenstein, and Catherine E Tucker, *Economic analysis of the digital economy*, University of Chicago Press, 2015.

Greenstein, Shane, "Building and Delivering the Virtual World: Commercializing Services for Internet Access," *The Journal of Industrial Economics*, 2000, *48* (4), 391–411.

Guidance for and FDA Staff on the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Guidance for and FDA Staff on the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, *Technical Report, Food and Drug Administration: Center for Devices and Radiological Health 2014.*

Guidance for Industry and FDA Staff on the Content of Premarket Submissions for Software Contained in Medical Devices

Guidance for Industry and FDA Staff on the Content of Premarket Submissions for Software Contained in Medical Devices, Technical Report, Food and Drug Administration: Center for Devices and Radiological Health 2005.

Guidance for Industry and Food and Drug Administration Staff on Postmarket Management of Cybersecurity in Medical Devices

Guidance for Industry and Food and Drug Administration Staff on Postmarket Management of Cybersecurity in Medical Devices, *Technical Report, Food and Drug Administration: Center for Devices and Radiological Health 2016.*

Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off the-Shelf (OTS) Software

Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off the-Shelf (OTS) Software, Technical Report, Food and Drug Administration: Center for Devices and Radiological Health 2005.

Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices

Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, *Technical Report, Food and Drug Administration: Center for Devices and Radiological Health 1999.*

Hall, Bronwyn H and Josh Lerner, *"The financing of R&D and innovation," in "Handbook of the Economics of Innovation," Vol. 1, Elsevier, 2010, pp. 609–639.*

Hao, Kenneth Y. and Adam B. Jaffe, *"Effect Of Liquidity On Firms' R&D Spending," Economics of Innovation and New Technology, 1993, 2 (4), 275–282.*

Harris, Robert S., Tim Jenkinson, and Steven N. Kaplan, *"Private Equity Performance: What Do We Know?," The Journal of Finance, 2014, 69 (5), 1851–1882.*

Helfat, Constance E, *"Know-how and asset complementarity and dynamic capability accumulation: the case of R&D," Strategic Management Journal, 1997, 18 (5), 339–360.*

Henderson, Rebecca and Iain Cockburn, *"Scale, Scope, and Spillovers: The Determinants of Research Productivity in Drug Discovery," RAND Journal of Economics, 1996, 27 (1), 32–59.*

Jaffe, Adam B., Manuel Trajtenberg, and Rebecca Henderson, *"Geographic Localization of Knowledge Spillovers as Evidenced by Patent Citations," The Quarterly Journal of Economics, 08 1993, 108 (3), 577–598.*

King, Andrew A and Christopher L Tucci, *"Incumbent entry into new market niches: The role of experience and managerial choice in the creation of dynamic capabilities," Management Science, 2002, 48 (2), 171–186.*

Korteweg, Arthur and Stefan Nagel, *"Risk-Adjusting the Returns to Venture Capital," The Journal of Finance, 2016, 71 (3), 1437–1470.*

Kortum, Samuel and Josh Lerner, *Does venture capital spur innovation? 2001.*

Kramer, Daniel B, Shuai Xu, and Aaron S Kesselheim, *"Regulation of medical devices in the United States and European Union," 2012.*

Lee, Jinhyung, Yong-Fang Kuo, and James S. Goodwin, *"The effect of electronic medical record adoption on outcomes in US hospitals," BMC Health Services Research, Feb 2013, 13 (1), 39.*

Lin, Sunny C, Ashish K Jha, and Julia Adler-Milstein, *"Electronic health records associated with lower hospital mortality after systems have time to mature," Health Affairs, 2018, 37 (7), 1128–1135.*

Maisel, William H, *"Medical device regulation: an introduction for the practicing physician," Annals of Internal Medicine, 2004, 140 (4), 296–302.*

Makower, Josh, *"Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation," in "The Structure of the MedTech Innovation Ecosystem" 2010.*

Mariani, Myriam, *"What determines technological hits?: Geography versus firm competencies," Research Policy, 2004, 33 (10), 1565 – 1582.*

Miller, Amalia R and Catherine Tucker, *"Privacy protection, personalized medicine, and genetic testing," Management Science, 2017, 64 (10), 4648–4668.*

Morton, Fiona M. Scott, *"Entry Decisions in the Generic Pharmaceutical Industry," The RAND Journal of Economics, 1999, 30 (3), 421–440.*

Moser, Petra, Joerg Ohmstedt, and Paul W Rhode, *"Patent citations—an analysis of quality differences and citing practices in hybrid corn," Management Science, 2017, 64 (4), 1926–1940.*

National Health Expenditure Accounts Highlights

National Health Expenditure Accounts Highlights, Technical Report, Centers for Medicare and Medicaid Services 2016.

Nerkar, Atul and Peter W Roberts, "Technological and product-market experience and the success of new product introductions in the pharmaceutical industry," *Strategic Management Journal*, 2004, *25* (8-9), 779–799.

Newman, Lily H, "Medical Devices are the Next Security Nightmare," *WIRED*, Mar 2017.

Panzar, John C. and Robert D. Willig, "Economies of Scope," *The American Economic Review*, 1981, *71* (2), 268–272.

Sheen, Albert, "The Real Product Market Impact of Mergers," *The Journal of Finance*, 2014, *69* (6), 2651–2688.

Stern, Ariel Dora, "Innovation under regulatory uncertainty: evidence from medical technology," *Journal of public economics*, 2017, *145*, 181–200.

Tecco, Halle, "2016 year end funding report: a reality check for digital health," 2016. Online.

_ **and Megan Zweig**, "Digital Health Funding 2017 Midyear Review: A Record Breaking First Half," 2017. Online.

Teece, David J, "Towards an economic theory of the multiproduct firm," *Journal of Economic Behavior & Organization*, 1982, *3* (1), 39–63.

_ , "Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy," *Research policy*, 1986, *15* (6), 285–305.

Wachter, Robert M. and Michael D. Howell, "Resolving the Productivity Paradox of Health Information Technology: A Time for OptimismResolving the Productivity Paradox of Health Information TechnologyResolving the Productivity Paradox of Health Information Technology," *JAMA*, 07 2018, *320* (1), 25–26.

Wizemann, Theresa et al., *Public health effectiveness of the FDA 510 (k) clearance process: balancing patient safety and innovation: workshop report*, National Academies Press, 2010.

Figures

Figure 1: Device classification (example)

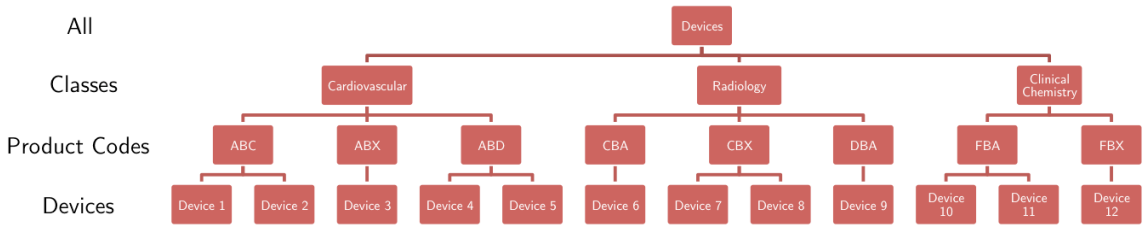


Figure 2: Number of newly approved digital devices by year

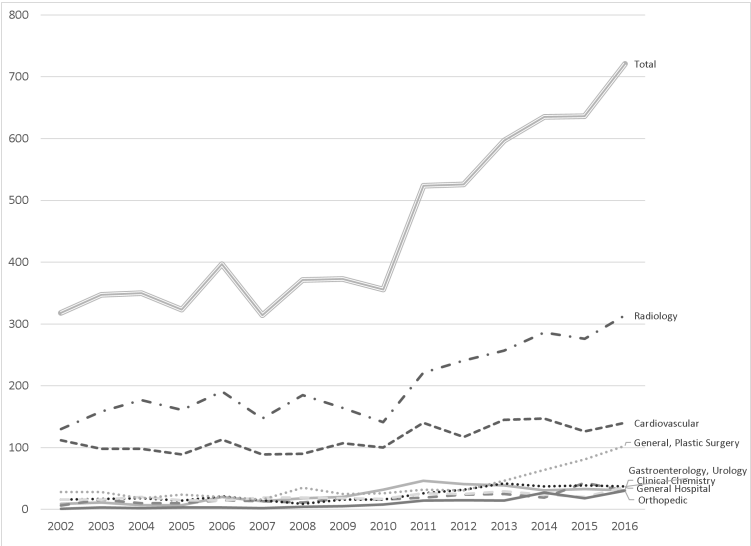


Figure 3a: Cumulative number of digital device product codes

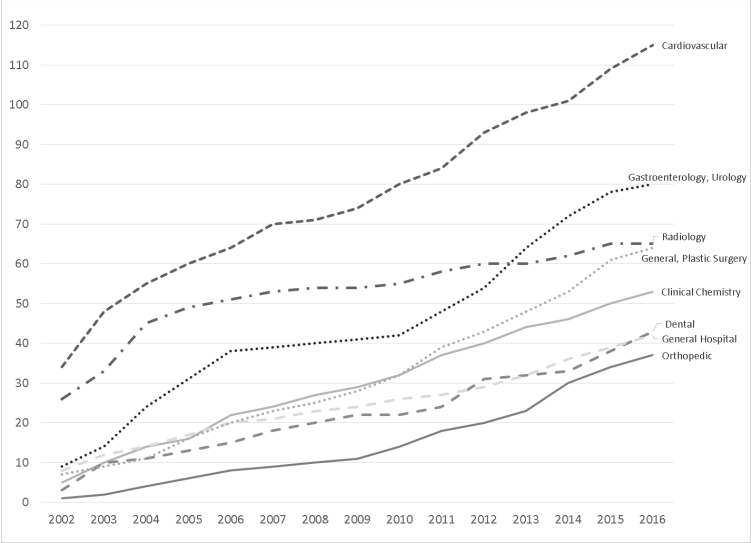


Figure 3b: Cumulative number of firms with digital devices

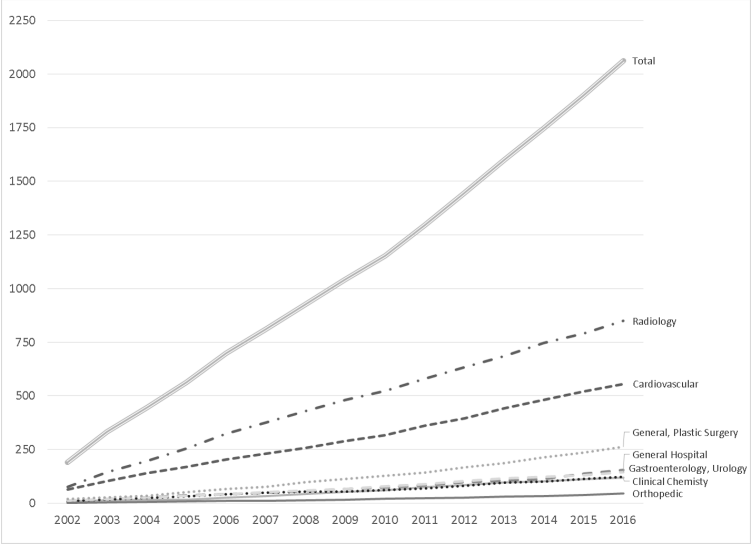


Figure 4a: Cumulative growth of digitized product codes (base year = 2002)

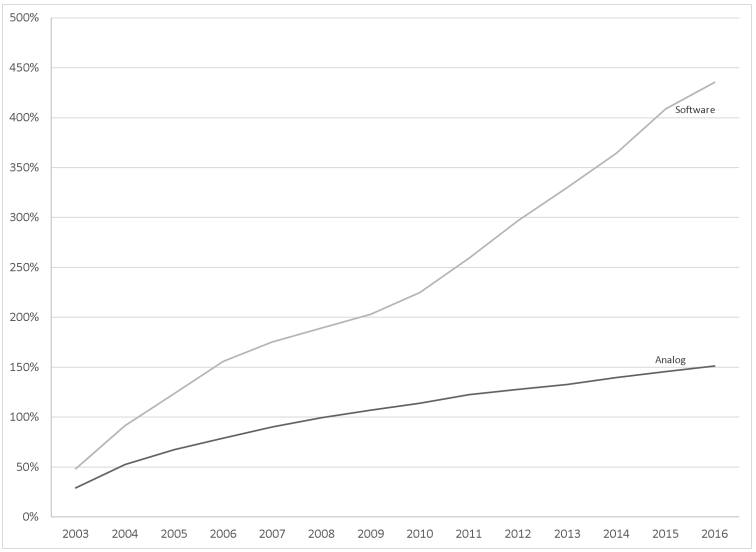
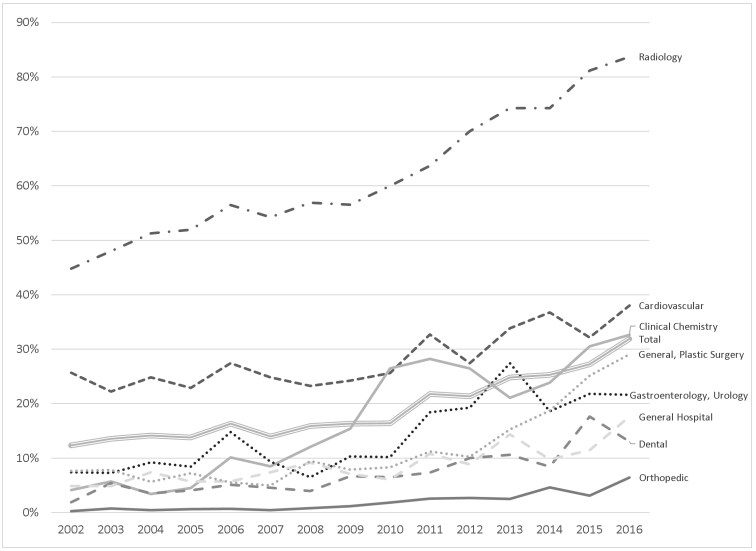


Figure 4b: Share of newly-approved digital devices (out of all approvals)



Tables

Table 1: Total counts of products by medical specialty (class) and overall

	Unique devices, full sample		Unique devices, regression sample*	
	n	%	n	%
Cardiovascular	6,092	17.0	3,884	17.5
Clinical Chemistry	2,353	6.6	1,318	6.2
Dental	3,942	11.0	2,282	10.9
Gastroenterology, Urology	2,571	7.2	1,647	8.2
General Hospital	3,779	10.6	1,920	9.3
General, Plastic Surgery	4,959	13.9	3,201	14.5
Orthopedic	7,228	20.2	5,346	22.4
Radiology	4,870	13.6	2,693	11.1
Total	35,794	100.0	22,291	100.0

*post 2004, US only

Table 2: Summary statistics

Metric	Sample Mean (± SD)
Firm experience	
Prior digital devices (past 3 years)	3.65 ± 12.54
Prior digital devices in class (past 3 years)	2.24 ± 9.05
Geography	
In digital device cluster (general, past 3 years), %	15.30
In digital device cluster (class-specific, past 3 years), %	44.39
Financial resources	
Publicly listed, %	32.32
VC funded (applicant), %	16.63
Total venture funding, cumulative	6.29 ± 23.91
Total venture funding if any, cumulative	37.81 ± 47.42

Non-binary variables are given as mean ± SD
n=22,291
n=3,706 for cases with any total venture funding
Prior digital devices calculated using keyword-based definition

Table 3: Control variables: year and product class

Logit model: digital device commercialization		
	(1)	(2)
Cardiovascular	0.240***	0.239***
	(0.045)	(0.046)
Clinical Chemistry	0.154***	0.156***
	(0.047)	(0.047)
Dental	0.054*	0.054*
	(0.024)	(0.024)
Gastroenterology, Urology	0.126***	0.126***
	(0.024)	(0.024)
General Hospital	0.092**	0.091**
	(0.033)	(0.033)
General, Plastic Surgery	0.097***	0.097***
	(0.023)	(0.023)
Radiology	0.615***	0.616***
	(0.079)	(0.080)
Year Fixed Effects	X	
	.	
Clearance year		0.013***
		(0.001)
N	22,291	22,291
Pseudo-R^2	0.2419	0.2402

* p<0.05, ** p<0.01, *** p<0.001

Logit model results for years 2005-2016, inclusive. Column 1 includes year fixed effects; Column 2 includes a linear time trend. Omitted class = Orthopedic Devices; omitted year (Column 1) = 2005, marginal effects reported. Digital devices defined based on keyword method.

Table 4: Geographic and within-firm expertise

Logit model: digital device commercialization								
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Ln of digital device experience	0.122***		0.077***					0.072***
	(0.009)		(0.012)					(0.011)
Ln of same-class digital device experience		0.123***	0.056***					0.043**
		(0.012)	(0.016)					(0.013)
Ln of state software employment				0.007			0.010*	0.005
				(0.005)			(0.005)	(0.004)
In digital device cluster (general)					0.080***		0.041***	0.010
					(0.013)		(0.009)	(0.008)
In digital device cluster (class-specific)						0.142***	0.133***	0.104***
						(0.010)	(0.009)	(0.008)
N	22,291	22,291	22,291	22,291	22,291	22,291	22,291	22,291

* p<0.05, ** p<0.01, *** p<0.001

Firm experience and cluster variables are defined based on three most recent calendar years. All models control for volume of firm commercialization activity in past three years and state-level device clusters (representing all state-level medical device device commercialization). All models also include a full set of time and product class fixed effects. Marginal effects reported; standard errors are clustered at the product code level. Digital devices defined based on keyword method.

Table 5: Financial resources

Logit model: digital device commercialization						
	(1)	(2)	(3)	(4)	(5)	(6)
Publicly listed firm	-0.004			-0.002	-0.003	0.004
	(0.010)			(0.010)	(0.010)	(0.012)
VC-funded firm		0.030*		0.030*		
		(0.012)		(0.013)		
Total VC funding, $ (Ln)			0.012**		0.012**	0.012**
			(0.004)		(0.004)	(0.004)
N	22,291	22,291	22,291	22,291	22,291	22,291

* p<0.05, ** p<0.01, *** p<0.001

All models include a full set of year and product class fixed effects. Column 6 includes additional controls for volume of firm commercialization activity in past three years and state-level device clusters (representing all state-level medical device device commercialization), as in Table 4. Marginal effects reported; standard errors are clustered at the product code level. Digital devices defined based on keyword method.

Table 6: Decomposition by device types

Logit model: digital device commercialization						
	Full Device Sample	Novel D.Devices	Follow-On D. Devices	All Non-Chem Devices	Single-Use Devices	Durable Devices
	(1)	(2)	(3)	(4)	(5)	(6)
Ln of digital device experience	0.078***	0.007***	0.075***	0.098***	0.022***	0.146***
	(0.011)	(0.002)	(0.011)	(0.011)	(0.006)	(0.026)
Ln of same-class digital device experience	0.040**	0.002	0.040**	0.021	0.016**	0.022
	(0.012)	(0.002)	(0.013)	(0.012)	(0.005)	(0.025)
In digital device cluster (general)	0.013	0.003	0.012	0.017*	-0.003	0.030
	(0.008)	(0.002)	(0.007)	(0.008)	(0.005)	(0.017)
In digital device cluster (class-specific)	0.104***	0.011***	0.098***	0.097***	0.028***	0.147***
	(0.007)	(0.002)	(0.007)	(0.008)	(0.005)	(0.017)
Publicly listed firm	0.039***	0.011***	0.034***	0.033***	0.007	0.053**
	(0.008)	(0.002)	(0.008)	(0.008)	(0.006)	(0.017)
Total VC funding, $ (Ln)	0.010***	0.002***	0.008**	0.011***	0.008***	0.010
	(0.003)	(0.001)	(0.003)	(0.003)	(0.002)	(0.006)
N	22,291	18,508	22,027	20,973	12,835	8,133

* p<0.05, ** p<0.01, *** p<0.001

Firm experience and cluster variables are defined based on three most recent calendar years. All models control for volume of firm commercialization activity in past three years and state-level device clusters (representing all state-level medical device device commercialization). All models also include a full set of time and product class fixed effects. Marginal effects reported; standard errors are clustered at the product code level. Digital devices defined based on keyword method.

Appendix A: The 510(k) Process

Appendix Exhibit 1: Extract from 510(k) Statement

510(K) SUMMARY JAN 1 1 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K073198

1. **Submitter's Identification:**

   Microlife Intellectual Property GmbH, Switzerland

   Espenstrasse 139
   9443 Widnau / Switzerland

   Date Summary Prepared: October 30, 2007

2. **Name of the Device:**

   Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1).

3. **Information for the 510(k) Cleared Device (Predicate Device):**

   Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3AC1-1 PC, K#060686.

4. **Device Description:**

   Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Home is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".
   The device has <DIAG> and <USUAL> measurement mode. In additional, the device can be used in connection with your personal computer **(PC)** running the WatchBP 1.0 software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

The information in this appendix is taken directly from the FDA's official description of the 510(k) (premarket notification) process (http://www.fda.gov/MedicalDevices/DeviceRegulation andGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/)

Introduction

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, 21 CFR 807 Subpart E describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act.

Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device. Once the device is determined to be SE, it can then be marketed in the U.S. The SE determination is usually made within 90 days and is made based on the information submitted by the submitter.

Please note that FDA does not perform 510(k) pre-clearance facility inspections. The submitter may market the device immediately after 510(k) clearance is granted. The manufacturer should be prepared for an FDA quality system (21 CFR 820) inspection at any time after 510(k) clearance.

What is Substantial Equivalence

A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;

or

- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA;

- does not raise new questions of safety and effectiveness; **and**
- demonstrates that the device is at least as safe and effective as the legally marketed device.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

A device may not be marketed in the U.S. until the submitter receives a letter declaring the device substantially equivalent. If FDA determines that a device is not substantially equivalent, the applicant may:

- resubmit another 510(k) with new data,
- request a Class I or II designation through the de novo process
- file a reclassification petition, or
- submit a premarket approval application (PMA).

Who is Required to Submit a 510(k)

The Act and the 510(k) regulation (21 CFR 807) do not specify who must apply for a 510(k). Instead, they specify which actions, such as introducing a device to the U.S. market, require a 510(k) submission.

The following four categories of parties must submit a 510(k) to the FDA:

1. Domestic manufacturers introducing a device to the U.S. market;

Finished device manufacturers must submit a 510(k) if they manufacture a device according to their own specifications and market it in the U.S. Accessories to finished devices that are sold to the end user are also considered finished devices. However, manufacturers of device components are not required to submit a 510(k) unless such components are promoted for sale to an end user as replacement parts. Contract manufacturers, those firms that manufacture devices under contract according to someone else? s specifications, are not required to submit a 510(k).

2. Specification developers introducing a device to the U.S. market;

A specification developer develops the specifications for a finished device, but has the device manufactured under contract by another firm or entity. The specification developer submits the 510(k), not the contract manufacturer.

3. Repackers or relabelers who make labeling changes or whose operations significantly affect the device.

Repackagers or relabelers may be required to submit a 510(k) if they significantly change the labeling or otherwise affect any condition of the device. Significant labeling changes may include modification of manuals, such as adding a new intended use, deleting or adding warnings, contraindications, etc. Operations, such as sterilization, could alter the condition of the device. However, most repackagers or relabelers are not required to submit a 510(k).

4. Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

Please note that all manufacturers (including specification developers) of Class II and III devices and select Class I devices are required to follow design controls (21 CFR 820.30) during the development of their device. The holder of a 510(k) must have design control documentation available for FDA review during a site inspection. In addition, any changes to the device specifications or manufacturing processes must be made in accordance with the Quality System regulation (21 CFR 820) and may be subject to a new 510(k). Please see our guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device."

When a 510(k) is Required

A 510(k) is required when:

1. Introducing a device into commercial distribution (marketing) for the first time. After May 28, 1976 (effective date of the Medical Device Amendments to the Act), anyone who wants to sell a device in the U.S. is required to make a 510(k) submission at least 90 days prior to offering the device for sale, even though it may have been under development or clinical investigation before that date. If your device was not marketed by your firm before May 28, 1976, a 510(k) is required.

2. You propose a different intended use for a device which you already have in commercial distribution. The 510(k) regulation (21 CFR 807) specifically requires a 510(k) submission for a major change or modification in intended use. Intended use is indicated by claims made for a device in labeling or advertising. Most, if not all changes in intended use will require a 510(k). Please note that prescription use to over the counter use is a major change in intended use and requires the submission of a new 510(k).

3. There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness. The burden is on the 510(k) holder to decide whether or not a modification could significantly affect safety or effectiveness of the device. Any modifications must be made in accordance with the Quality System regulation, 21 CFR 820, and recorded in the device master record and change control records. It is recommended that the justification for submitting or not submitting a new 510(k) be recorded in the change control records.

A new 510(k) submission is required for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use. See Is a new 510(k) required for a modification to the device? for additional information.

When a 510(k) is Not Required

The following are examples of when a 510(k) is not required.

1. You sell unfinished devices to another firm for further processing or sell components to be used in the assembling of devices by other firms. However, if your components are to be sold directly to end users as replacement parts, a 510(k) is required.

2. Your device is not being marketed or commercially distributed. You do not need a 510(k) to develop, evaluate, or test a device. This includes clinical evaluation. Please note that if you perform clinical trials with your device, you are subject to the Investigational Device Exemption (IDE) regulation (21 CFR 812).

3. You distribute another firm's domestically manufactured device. You may place a label on the device, "Distributed by ABC Firm" or "Manufactured for ABC Firm," (21 CFR 801.1) and sell it to end users without submission of a 510(k).

4. In most cases, if you are a repackager or a relabeler you are not required to submit a 510(k) if the existing labeling or condition of the device is not significantly changed. The labeling should be consistent with the labeling submitted in the 510(k) with the same indications for use and warnings and contraindications.

5. Your device was legally in commercial distribution before May 28, 1976 and you have documentation to prove this. These devices are "grandfathered" and have Preamendment Status. You do not have to submit a 510(k) unless the device has been significantly modified or there has been a change in its intended use.

6. The device is made outside the U.S. and you are an importer of the foreign made medical device. A 510(k) is not required if a 510(k) has been submitted by the foreign manufacturer and received marketing clearance. Once the foreign manufacturer has received 510(k) clearance for the device, the foreign manufacturer may export his device to any U.S. importer.

7. Your device is exempted from 510(k) by regulation (21 CFR 862-892). That is, certain Class I or II devices can be marketed for the first time without having to submit a 510(k). A list of the Class I and II exempted devices can be found on Medical Device Exemptions 510(k) and GMP Requirements. However, if the device exceeds the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9), such as the device has a new intended use or operates using a different fundamental scientific technology than a legally marketed device in that generic type of device, or the device is a reprocessed single-use device, then a 510(k) must be submitted to market the new device.

Preamendment Devices

The term "preamendments device" refers to devices legally marketed in the U.S. by a firm before May 28, 1976 and which have not been:

- significantly changed or modified since then; and

- for which a regulation requiring a PMA application has not been published by FDA.

Devices meeting the above criteria are referred to as "grandfathered" devices and do not require a 510(k). The device must have the same intended use as that marketed before May 28, 1976. If the device is labeled for a new intended use, then the device is considered a new device and a 510(k) must be submitted to FDA for marketing clearance.

Please note that you must be the owner of the device on the market before May 28, 1976, for the device to be grandfathered. If your device is similar to a grandfathered device and marketed after May 28, 1976, then your device does NOT meet the requirements of being grandfathered and you must submit a 510(k). In order for a firm to claim that it has a preamendments device, it must demonstrate that its device was labeled, promoted, and distributed in interstate commerce for a specific intended use and that intended use has not changed. See Preamendment Status for information on documentation requirements.

Third Party Review Program

The Center for Devices and Radiological Health (CDRH) has implemented a Third Party Review Program. This program provides an option to manufacturers of certain devices of submitting their 510(k) to private parties (Recognized Third Parties) identified by FDA for review instead of submitting directly to CDRH. For more information on the program, eligible devices and a list of Recognized Third Parties go to Third Party Review Program Information page.

Appendix B: The PMA Process

Appendix Exhibit 2: Extract from PMA Statement

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Continuous Glucose Monitoring (CGM) System
Device Trade Name:	iPro2 Continuous Glucose Monitoring (CGM) System
Device Procode:	MDS
Applicant's Name and Address:	Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325
Date(s) of Panel Recommendation:	None

Premarket Approval Application (PMA) Number: P150029

Date of FDA Notice of Approval: June 17, 2016

Priority Review: *Not Applicable*

II. INDICATIONS FOR USE

iPro2 CGM System (MMT-7745)
The iPro2 Recorder is to be used with either Enlite sensor or Sof-Sensor and is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using a standard home glucose-monitoring device. The information collected by the iPro2 Recorder may be uploaded to a computer (with Internet access) and reviewed by healthcare professionals. This information may allow identification of patterns of glucose level excursions above or below the desired range, facilitating therapy adjustments which may minimize these excursions.

VI. Software

The current software version for the iPro2 CGM system is v1.1A. Software verification and validation were carried out in accordance with the FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: General Principles of Software Validation: Final Guidance for Industry and FDA Staff (2002).* Software development activities included establishing detailed software requirements, linking requirements with associate verification tests, software code reviews, unit testing, system level testing and defect tracking and dispositioning to ensure the software conforms to patient needs and intended uses. Software was previously reviewed under P980022/S071.

VII. Human Factors Testing

The sponsor referenced human factors testing from previous submissions (P980022 and P120010) and provided new testing to support the proposed system configuration. New testing included the following:

- Evaluation of tasks regarding the removal of the iPro2 recorder from the Enlite sensor and inspection of fluids on the recorder before initiating contact with the iPro2 docking station.
- Evaluation of specific tasks performed in the software.

PMA P150029: FDA Summary of Safety and Effectiveness Data Page 7

The information in this appendix is taken directly from the FDA?s official description of

the Premarket Approval process (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm).

Overview

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III preamendment devices may require a Class III 510(k). See "Historical Background" for additional information.

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device. The PMA owner, however, can authorize use of its data by another.

The PMA applicant is usually the person who owns the rights, or otherwise has authorized access, to the data and other information to be submitted in support of FDA approval. This person may be an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. The applicant is often the inventor/developer and ultimately the manufacturer.

FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission. After FDA notifies the applicant that the PMA has been approved or denied, a notice is published on the Internet (1) announcing the data on which the decision is based, and (2) providing interested persons an opportunity to petition FDA within 30 days for reconsideration of the decision.

The regulation governing premarket approval is located in Title 21 Code of Federal Regulations (CFR) Part 814, Premarket Approval. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act and cannot be marketed.

When a PMA is Required

PMA requirements apply to Class III devices, the most stringent regulatory category for medical devices. Device product classifications can be found by searching the Product Classification Database. The database search provides the name of the device, classification, and a link to the Code of Federal Regulations (CFR), if any. The CFR provides the device type name, identification of the device, and classification information.

A regulation number for Class III devices marketed prior to the 1976 Medical Device Amendments is provided in the CFR. The CFR for these Class III devices that require a PMA

states that the device is Class III and will provide an effective date of the requirement for PMA. If the regulation in the CFR states that "No effective date has been established of the requirement for premarket approval," a Class III 510(k) should be submitted.

Please note that PMA devices often involve new concepts and many are not of a type marketed prior to the Medical Device Amendments. Therefore, they do not have a classification regulation in the CFR. In this case, the product classification database will only cite the device type name and product code. If it is unclear whether the unclassified device requires a PMA, use the three letter product code to search the Premarket Approval (PMA) database and the 510(k) Premarket Notification database. These databases can also be found by clicking on the hypertext links at the top of the product classification database web page. Enter only the three letter product code in the product code box. If there are 510(k)?s cleared by FDA and the new device is substantially equivalent to any of these cleared devices, then the applicant should submit a 510(k). Furthermore, a new type of device may not be found in the product classification database. If the device is a high risk device (supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury) and has been found to be not substantially equivalent (NSE) to a Class I, II, or III [Class III requiring 510(k)] device, then the device must have an approved PMA before marketing in the U.S. Some devices that are found to be not substantially equivalent to a cleared Class I, II, or III (not requiring PMA) device, may be eligible for the de novo process as a Class I or Class II device. For additional information on the de novo process, see the guidance "New section 513(f)(2) - Evaluation of Automatic Class III Designation: Guidance for Industry and CDRH Staff" as well as the Evaluation of Automatic Class III Designation (De Novo) Summaries webpage.

Devices Used in Blood Establishments

The Center for Biologic, Evaluation, Research (CBER) has expertise in blood, blood products, and cellular therapies as well as the integral association of certain medical devices with these biological products. To utilize this expertise marketing and investigational device submissions (Premarket Notification, Premarket Approval, and Investigational Device Exemption) for medical devices associated with the blood collection and processing procedures as well as those associated with cellular therapies are reviewed by CBER. Although these products are reviewed by CBER, the medical device laws and regulations still apply. The list of medical devices reviewed by CBER are available on the Internet. In addition to CDRH guidance on Premarket Approval, specific medical device guidance for devices reviewed by CBER is available at online or by contacting:

Center for Biologics Evaluation and Research
Office of Communication, Training and Manufacturers Assistance (HFM-43)
1401 Rockville Pike, Room 200N
Rockville, MD 20852-1448 U.S.A.
Telephone Number: 301-827-2000 or 800-835-4709
Fax Number: 301-827-3843

Data Requirements

A Premarket Approval (PMA) application is a scientific, regulatory documentation to FDA to demonstrate the safety and effectiveness of the class III device. There are administrative elements of a PMA application, but good science and scientific writing is a key to the approval of PMA application. If a PMA application lacks elements listed in the administrative checklist, FDA will refuse to file a PMA application and will not proceed with the in-depth review of scientific and clinical data. If a PMA application lacks valid clinical information and scientific analysis on sound scientific reasoning, it could impact FDA's review and approval. PMA applications that are incomplete, inaccurate, inconsist, omit critical information, and poorly organized have resulted in delays in approval or denial of PMA applications. Manufacturers should perform a quality control audit of a PMA application before sending it to FDA to assure that it is scientifically sound and presented in a well organized format.

Technical Sections: The technical sections containing data and information should allow FDA to determine whether to approve or disapprove the application. These sections are usually divided into non-clinical laboratory studies and clinical investigations.

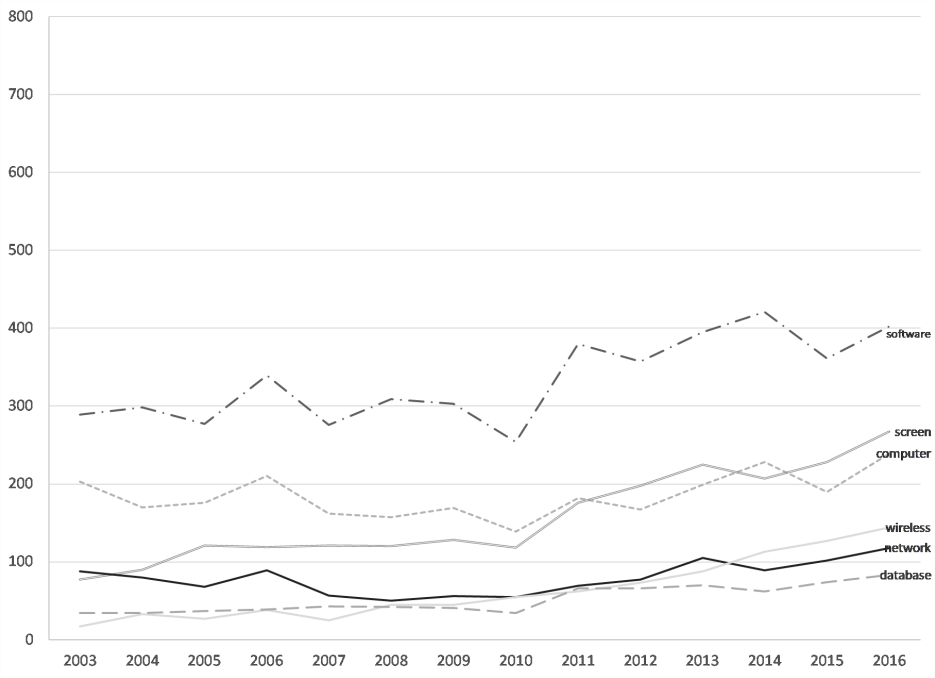
Non-clinical Laboratory Studies Section: Non-clinical laboratory studies section includes information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests. Non-clinical studies for safety evaluation must be conducted in compliance with 21 CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies). To assist you in determining the appropriate preclinical bench studies for your device, refer to the applicable guidance documents and standards identified in the Product Classification database for your device. You may also seek input from the review branch via the Pre-Submission Program.

Clinical Investigations Section: Clinical investigations section includes study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations. Any investigation conducted under an Investigational Device Exemption (IDE) must be identified as such.

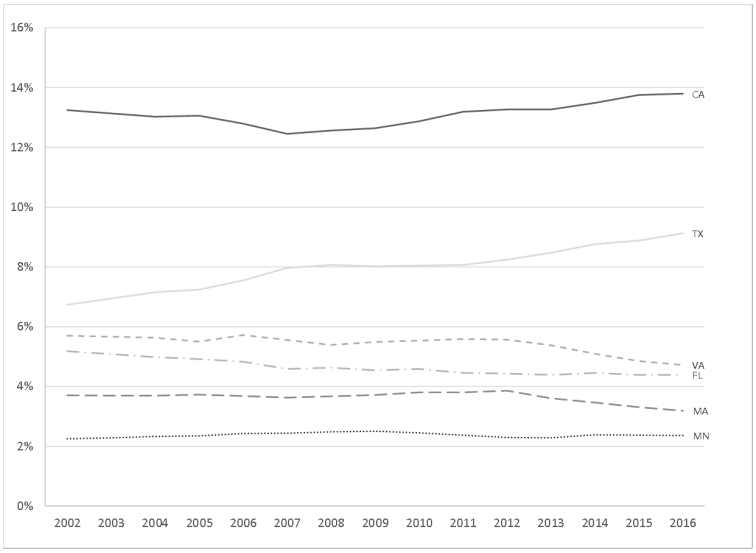
Like other scientific reports, FDA has observed problems with study designs, study conduct, data analyses, presentations, and conclusions. Investigators should always consult all applicable FDA guidance documents, industry standards, and recommended practices. Numerous device-specific FDA guidance documents that describe data requirements are available. Study protocols should include all applicable elements described in the device-specific guidance documents.

Appendix C: Additional tables and results

Appendix Figure I: New digital devices

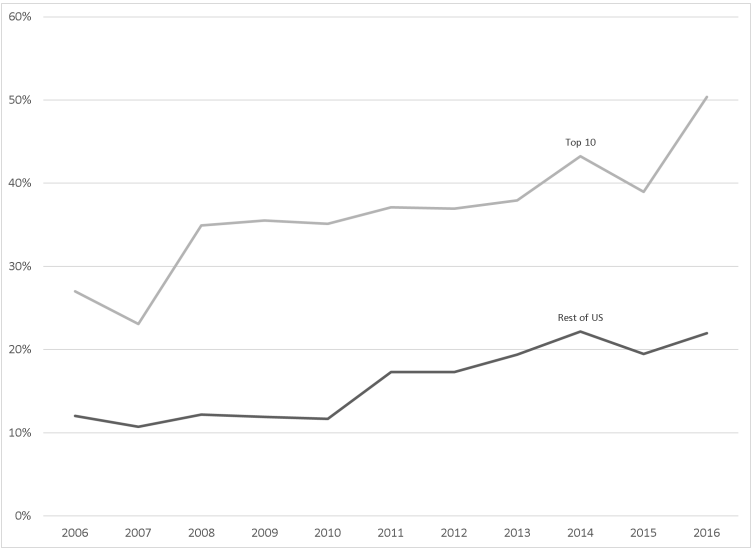


Appendix Figure II: Variation in state share of software engineers*

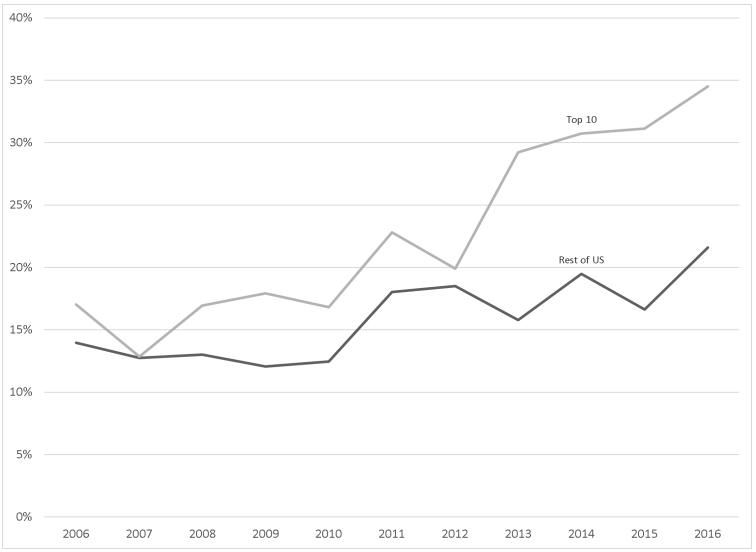


*linear imputation for years 2002-2004 and 2016

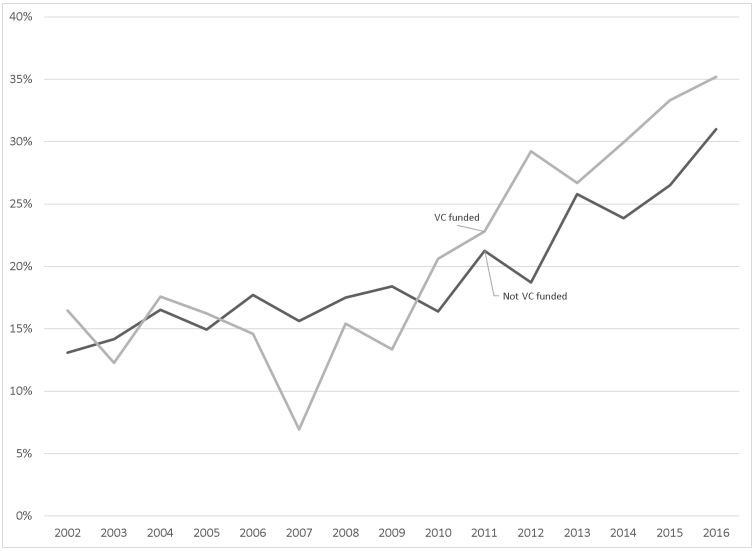
Appendix Figure III: Share of digital devices in *general* clusters vs. rest



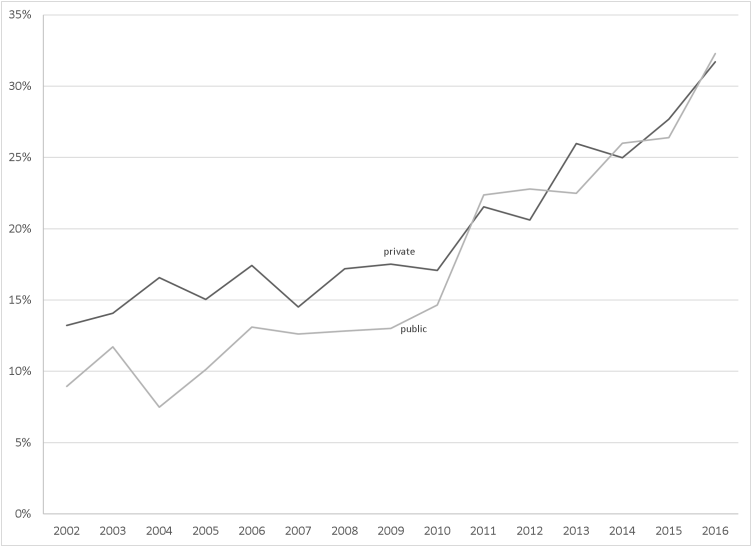
Appendix Figure IV: Share of digital devices in *class-specific* clusters vs. rest



Appendix Figure V: Share of digital devices: VC vs. non-VC-funded private firms



Appendix Figure VI: Share of digital devices: publicly-listed vs. private firms



Appendix Table I: Machine readable documents by sample year

Year	Readable Documents	Total Products	% Readable
2002	2,573	2,587	99.5
2003	2,565	2,579	99.5
2004	2,476	2,505	98.8
2005	2,338	2,364	98.9
2006	2,430	2,450	99.2
2007	2,245	2,318	96.9
2008	2,333	2,382	97.9
2009	2,287	2,333	98.0
2010	2,168	2,242	96.7
2011	2,405	2,452	98.1
2012	2,466	2,502	98.6
2013	2,404	2,428	99.0
2014	2,509	2,552	98.3
2015	2,334	2,408	96.9
2016	2,261	2,328	97.1
Total	35,794	36,496	98.1

Based on 8 most common medical specialty areas (classes).

Appendix Table II: Keywords and overlap of each with MTI classification of software devices

Keyword (& acronyms thereof)*	Total devices	% Flagged by MTI as "software"
data	18,894	20%
internet	9,840	17%
software	6,788	73%
imaging	5,470	49%
display	5,107	50%
interface	3,728	40%
digital	3,249	47%
computer	2,779	58%
screen	2,278	49%
transmission	1,798	41%
platform	1,361	47%
network	1,187	62%
wireless	906	48%
database	757	57%
server	731	70%
programmable	714	48%
microprocessor	593	33%
digitally	464	27%
bit	418	58%
processor	381	48%
analog	359	39%
digitalimage	312	54%
ethernet	291	58%
bluetooth	287	35%
cpu	277	50%
LAN	232	66%
datastorage	223	57%
datacollection	221	45%
informationsyste	193	69%
touchscreen	183	31%
download	180	59%
online	161	48%
IT	133	39%
digitaldata	125	54%
harddisk	116	73%
bandwidth	110	63%

This list includes all keywords found in >100 unique product descriptions.

Appendix Table III: Control variables: year and product class, MTI

Logit model: digital device commercialization		
	(1)	(2)
Cardiovascular	0.162***	0.162***
	(0.033)	(0.033)
Clinical Chemistry	0.099***	0.099***
	(0.028)	(0.029)
Dental	0.038*	0.038*
	(0.017)	(0.017)
Gastroenterology, Urology	0.062***	0.062***
	(0.014)	(0.014)
General Hospital	0.050*	0.050*
	(0.020)	(0.019)
General, Plastic Surgery	0.054***	0.053***
	(0.014)	(0.014)
Radiology	0.515***	0.516***
	(0.073)	(0.074)
N	22,291	22,291
Pseudo-R^2	0.2349	0.2339

* p<0.05, ** p<0.01, *** p<0.001

Logit model results for years 2005-2016, inclusive. Column 1 includes year fixed effects; Column 2 includes a linear time trend. Omitted class = Orthopedic Devices; omitted year (Column 1) = 2005, marginal effects reported. Digital devices defined based on MTI method.

Appendix Table IV: Geographic and within-firm expertise, MTI

Logit model: digital device commercialization								
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Ln of digital device experience	0.080***		0.054***					0.051***
	(0.007)		(0.009)					(0.008)
Ln of same-class digital device experience		0.081***	0.033*					0.025*
		(0.009)	(0.013)					(0.011)
Ln of state software employment				0.006			0.009	0.005
				(0.004)			(0.005)	(0.004)
In digital device cluster (general)					0.056***		0.033***	0.012
					(0.010)		(0.007)	(0.007)
In digital device cluster (class-specific)						0.091***	0.085***	0.067***
						(0.009)	(0.009)	(0.007)
N	22,291	22,291	22,291	22,291	22,291	22,291	22,291	22,291

* p<0.05, ** p<0.01, *** p<0.001

Firm experience and cluster variables are defined based on three most recent calendar years. All models control for volume of firm commercialization activity in past three years and state-level device clusters (representing all state-level medical device device commercialization). All models also include a full set of time and product class fixed effects. Marginal effects reported; standard errors are clustered at the product code level. Digital devices defined based on MTI method.

Appendix Table V: Financial resources, MTI

Logit model: digital device commercialization						
	(1)	(2)	(3)	(4)	(5)	(6)
Publicly listed firm	-0.019*			-0.018*	-0.018*	-0.017
	(0.008)			(0.008)	(0.008)	(0.009)
VC-funded firm		0.015		0.013		
		(0.010)		(0.010)		
Total VC funding, $ (Ln)			0.007*		0.007	0.007
			(0.003)		(0.004)	(0.003)
N	22,291	22,291	22,291	22,291	22,291	22,291

* p<0.05, ** p<0.01, *** p<0.001

All models include a full set of year and product class fixed effects. Column 6 includes additional controls for volume of firm commercialization activity in past three years and state-level device clusters (representing all state-level medical device device commercialization), as in Table 4. Marginal effects reported; standard errors are clustered at the product code level. Digital devices defined based on MTI method.

Appendix Table VI: Decomposition by device types, MTI

Logit model: digital device commercialization						
	Full Device Sample	Novel D.Devices	Follow-On D. Devices	All Non-Chem Devices	Single-Use Devices	Durable Devices
	(1)	(2)	(3)	(4)	(5)	(6)
Ln of digital device experience	0.055***	0.004*	0.053***	0.070***	0.014***	0.109***
	(0.008)	(0.002)	(0.009)	(0.010)	(0.004)	(0.021)
Ln of same-class digital device experience	0.024*	0.000	0.024*	0.009	0.009*	0.016
	(0.011)	(0.002)	(0.011)	(0.012)	(0.004)	(0.024)
In digital device cluster (general)	0.013*	0.002	0.012	0.016*	-0.002	0.025
	(0.007)	(0.002)	(0.006)	(0.007)	(0.003)	(0.015)
In digital device cluster (class-specific)	0.067***	0.007***	0.062***	0.064***	0.014***	0.099***
	(0.007)	(0.002)	(0.007)	(0.007)	(0.003)	(0.016)
Publicly listed firm	0.022***	0.005**	0.019**	0.019**	0.005	0.017
	(0.007)	(0.002)	(0.007)	(0.007)	(0.004)	(0.016)
Total VC funding, $ (Ln)	0.006*	0.002**	0.004	0.006*	0.005***	0.004
	(0.003)	(0.001)	(0.003)	(0.003)	(0.001)	(0.006)
N	22,291	19,590	22,108	20,973	12,835	8,133

* p<0.05, ** p<0.01, *** p<0.001

Firm experience and cluster variables are defined based on three most recent calendar years. All models control for volume of firm commercialization activity in past three years and state-level device clusters (representing all state-level medical device device commercialization). All models also include a full set of time and product class fixed effects. Marginal effects reported; standard errors are clustered at the product code level. Digital devices defined based on keyword method.