Competition and Innovation: Evidence from Third-Party Reprocessing in the Medical Device Industry

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Abstract

Healthcare is projected to soon become the industry with the largest amount of spending on research and development in the world. While competition has the potential to catalyze the development of new healthcare technologies and drive down costs, increases in competition have also been thought to hinder innovation as a result of thinner profit margins and reduced incentives. I estimate whether and to what extent competition in the medical device industry promotes innovation. Using Food and Drug Administration data on medical device applications from 1976 to 2019, I examine how original equipment manufacturers respond to the entry of third-party reprocessed devices. I find that, when controlling for year and medical specialty, the introduction of a reprocessed device leads to an almost five-fold increase in new device applications by original manufacturers after both one and two years. These results suggest that an increase in competition within the medical device market has spurred innovation and the development of new technologies.

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I. Introduction

In 2017, the United States spent $10,209 per person, amounting to roughly $3.5 trillion total, on health expenditures (Committee for a Responsible Federal Budget [CRFB], 2018). A 2018 review published in the Journal of the American Medical Association found that healthcare spending in the United States was roughly twice as large as ten other high-income countries (CRFB, 2018). The high cost of the American healthcare system has often been justified as a natural product of the increased amount of development and innovation that American companies and researchers take on, with healthcare projected to soon become the industry with the largest amount of spending on research and development globally (Boehm, 2005; Jaruzelski, Chwalick, and Goehle, 2018). Increased competition has the potential to bring down prices, but previous literature finds the result might be a deterrence to innovation as a result of thinner margins and less potential profit from the development of a new technology or product (Chen and & Schwartz, 2013). However not all competition is the same: researchers have also found that the entrance of remanufacturers, or reprocessors, firms that acquire used devices and refurbish them to be sold again, can spur an original manufacturer to innovate in order to produce a device which is harder and more expensive to reprocess (Majumder and Groenevelt, 2009). This thesis investigates how original equipment manufacturers of medical devices respond to an increase in competition. This paper will clearly delineate the positive effect that the entry of reprocessors as competitors to original equipment manufacturers has had on innovation in the medical device industry.

It's estimated that in a given year, between 4 and 6 percent of total spending on healthcare is put towards medical devices (Medicare Payment Advisory Commission [MEDPAC], 2017). While the medical device industry is dominated by a handful of larger firms, the marketplace has seen notable shifts leading to increased competition in the past two decades. Specifically, this competition has arisen between medical device "originators", those who produce new devices, and "reprocessors". Third-party reprocessors take used devices such as surgical catheters or laparoscopes that are disposed of by hospitals and sterilize, refurbish, and reset these devices. They then sell these reprocessed devices for a deep discount, averaging around half the price of a new device (*Medical Devices*, 2000). The effect of these discounts on the market has been clear, with the Government Accountability Office estimating that between 20 and 30 percent of American hospitals were using at least one type of reprocessed devices in 2000 (*Medical Devices*, 2000). In August 2018, the Association of Medical Device Reprocessors (AMDR) reported that 95 percent

of the US News and World Report "Honor Roll" hospitals were working with at least one third-party reprocessing firm (Association of Medical Device Reprocessors [AMDR], 2018). The increasing competition has demonstrably impacted the medical device market, causing original manufacturers producing devices that contain "kill switches", making reprocessing of the devices more difficult (Chamoff, 2015). While originators have tried to compete by producing devices with these kill switches as well as by acquiring reprocessing firms, it has not yet been understood if originators are responding to the increased competition by innovating.[2] This is the first paper to assess the effects of competition on innovation in the American medical device industry.

I will begin my analysis by discussing relevant literature regarding competition and innovation. I will then lay out the theory behind my analysis as well as an empirical framework which will serve as the basis of my model. After discussing the model and the data that I use to study innovation, I will present my findings showing the positive effects of competition on innovation and will discuss implications of these findings as well as future pathways for research.

[2] In 2009, Stryker bought Ascent Healthcare Solutions, a reprocessor, and in 2011, Sterilmed, a reprocessor, was acquired by Ethicon Endo-Surgery, a subsidiary of Johnson & Johnson.

II. Literature Review

Literature regarding competition and innovation in the medical device industry is quite limited as the field has not yet been studied in depth. I contribute to the body of literature in healthcare competition in three significant ways: I provide an empirical study of the effects of remanufacturing, an analysis of innovation and competition in the medical device industry, and an analytical model to study innovation in the American medical device industry.

Research into the competitive effects of remanufacturers as well as the relationship between competition and the development of new technology has predominantly occurred in a theoretical lens. These theoretical studies most often look at a two-period model with one originator and one or more remanufacturers (Majumder and Groenevelt, 2009; Ferrer and Swaminathan, 2006). Ferrer and Swaminathan (2006) and Majumder and Groenevelt (2009) both focus on pricing and allocation strategies employed by both the reprocessor and original equipment manufacturer in periods one and two but use two separate models to determine their optimal strategies. Majumder and Groenevelt (2009) find that an increase in reprocessing costs would benefit the originator at the expense of the third-party reprocessor. Extending beyond a simple two-period model, Mitra and Webster (2008) study the potential use of government subsidies to maximize profits for both the originator and remanufacturer, and Mitra (2016) determines the viability of remanufacturing by a firm to gain a competitive advantage in a duopoly using both a single-period and two-period model. While efforts to understand the competitive effects of remanufacturing by either a third-party remanufacturer or an originator are clear and offer the nuance necessary to understand their implications in real markets, my research adds to this body of work by providing an empirical analysis of competitive responses to remanufacturing.

There have been multiple noteworthy studies regarding the connections between an increase in competition and the potential for innovation, specifically as they relate to monopolies. These studies are valuable in the context of my research because they help to explain the effects of the entrance of a price competitor in a highly concentrated market. Their work has determined that monopolists who are unthreatened by the entrance of competitors are less incentivized to develop “process innovations” than perfectly competitive firms due to a lack of price competition and more inertia to innovation (Arrow, 1962). Literature has since added nuance to this view, finding that the landscape most conducive to the development of new products is the case of a monopolist who is threatened by the entrance of competitors, especially when the monopolist has

the choice of maintaining a monopoly over the new product as well (Greenstein and Ramey, 1998; Chen and Schwartz, 2013). The basis for their conclusions is that a threatened monopolist not only has relatively larger profits to invest in innovation but also a greater incentive to preserve their monopoly than a firm operating under perfect competition. This lends credence to my hypothesis that as a response to the growth of remanufacturers, medical device originators will elect to develop new devices which are both improvements on previous iterations and harder to remanufacture. Despite heavy theoretical evidence to the contrary, a recent empirical study by Autor, Dorn, Hanson, Pisano, and Shu (2016) finds that an increase in foreign competition from China in the manufacturing sector has actually stifled domestic innovation and patent production. As the paper by Autor et al. (2016) is one of few empirical studies on innovation and competition, this research adds to the field in its use of empirical evidence to show the effects of the introduction of new firms on product development throughout the rest of the medical device industry.

When looking at literature on innovation in healthcare more broadly, most work has focused on the pharmaceutical industry with interests in the connections between market size, profit, and the elasticity of innovation, rather than competition between firms (Acemoglu and Linn, 2004; Blume-Kohout and Sood, 2013; Dubois, Mouzon, Scott-Morton, and Seabright, 2015). They often utilize an "elasticity of innovation" to determine how marginal changes in input parameters affect product innovations. However, Dranove, Garthwaite, and Hermosilla (2014) develop a novel model, attempting to differentiate between innovations that provide "social value" and those that do not. While not directly tied to my field of study, this literature is helpful in understanding potential exogenous changes to innovation as well as in providing insight into product development, competition, and regulation within the healthcare industry.

Though limited, there is literature regarding innovation in the medical device industry. Pammolli, et al. (2005) provide the most comprehensive overview of the state of research and development as well as production in the industry. The authors study innovation in the sector in order to compare research and development investments between industries as well as between countries. They do so by analyzing patent data to see the number of patents applied for by medical device firms as well as the number of citations that each one of those medical devices has, with the implication that a more cited patent reflects a more substantial innovation. The patent data analyses used by Pammolli, et al. (2005) were also adopted by Autor, et al. (2016) in studying the effects of foreign competition on domestic innovation. While the report provides helpful

background, its scope is limited to the device market in Europe and to originators solely. Additionally, the use of patent data cannot be effectively translated to the American medical device market as patents are less likely to be used in the development of medical devices (Kahn, 1991). My research uses an approach more suited to the American medical device industry, which makes up over 40 percent of the global medical device market, utilizing publicly available 510(k) data.

III. Theoretical Framework

A firm's decision to spend resources on research and development is dependent on a series of factors such as regulatory environments, market size, and industry competition, among others. In the context of competition from reprocessors of medical devices and changes in innovation by original manufacturers, I hypothesize that an increase in competition from reprocessors will lead to an increase in product development and greater 510(k) applications by originators.

Majumder and Groenevelt (2009) provide foundational theory on competitive decisions that are employed by originators as a result of the growth of remanufacturers. They demonstrate this relationship through a two-period model, considering the actions in both periods of one remanufacturer and one originator which can also remanufacture products. In the first period, only the originator manufactures and sells new items. In the second period, the originator can both manufacture new items and remanufacture used items, while the remanufacturer can only refurbish the used items. After determining Nash Equilibrium responses for multiple different scenarios in the second period, an optimal manufacturing decision for the originator is constructed across both periods. The demand of goods from each party, where p_i is the price charged and q_i is the total new quantity sold by player i (either L for the remanufacturer or O for the originator), is provided as

$$D_O(p_O, p_L) = A_O - B_O p_O + C_O p_L \tag{1}$$

$$D_L(p_O, p_L) = A_L - B_L p_L + C_L p_O \tag{2}$$

The remanufacturer optimizes according to their budget constraint in the second period, where ρ is the number of used devices available to each party

$$\Theta_L(\rho, p_O): max_{q_L, p_L}\ q_L(p_L - r_L),\ \ s.t.\ \ q_L \leq \rho \tag{3}$$

$$0 \leq q_L \leq D_L(p_O, p_L) \tag{4}$$

$$p_L \geq 0 \tag{5}$$

Simultaneously, the originator also optimizes according to their budget constraint, under the assumption that the cost of manufacturing a new item, c, is greater than the originator's cost of remanufacturing, r_O, and that the originator will remanufacture q_{OR} devices

$$\Theta_O(\rho, p_L): max_{q_O, q_{OR}, p_O} \ (p_O - c)q_O + (c - r_O)q_{OR}, \ \ s.t. \ \ q_{OR} \leq \rho \tag{6}$$

$$0 \leq q_{OR} \leq q_O \leq D_L(p_O, p_L) \tag{7}$$

$$p_O \geq 0 \tag{8}$$

Both the originator and the remanufacturer have multiple different optimal price and quantity levels based on their relative allocations of the used devices in the second period. Each party first optimizes their demand function and constraints by price and then produces the corresponding quantity. Different Nash Equilibrium scenarios can then be determined based on different allocations of used devices between the two parties.

After deciding the second period Nash Equilibrium, the originator seeks to maximize total profit over both periods as its first period manufacturing decisions will determine the number of used devices that can be manufactured in the second period. Thus, the two-period game can be reduced to an optimization of the number of devices available for remanufacture in period two, R. In Majumder and Groenevelt (2009), a range of potential outcomes for this game is determined using a variety of potential input parameters. They find that, among other results, when the reprocessor's cost of remanufacturing goes up, their profit goes down, and the originator's total profit goes up, with the conclusion being that an originator will be incentivized to increase the marginal cost of remanufacturing for the other party.

The model I construct builds on work done by Majumder and Groenevelt (2009) by looking at this question as a series of connected two-period games, where an originator produces original devices in both periods, while the remanufacturer begins reprocessing them in period two. I assume that the originator cannot remanufacture. In Period 1 of Game A, the originator begins to manufacture Device A and sell it to consumers. In period 2 of Game A, a remanufacturer enters and begins to reprocess Device A and directly compete with the originator. The response expected from the originator in Game B is to produce a new device, Device B, which is in some way technologically superior to Device A, such that consumer will prefer it. Doing so means that demand for both original and remanufactured versions of Device A will be equal to zero and the originator will regain a monopoly on the market in Period 1 of Game B. The reprocessor is expected to again enter in Period 2 of Game B.

This model is used to determine the relationship between Period 2 of Game A and Period 1 of Game B, using multiple years of reprocessed devices to account for the potential lag time between the introduction of a reprocessed device and a competitive response by an originator (Emergo Group, 2017).

IV. Data

Data Sources

All of the data used for this project was sourced from the OpenFDA public database, which is part of the Food and Drug Administration (FDA). From this page, I downloaded both 510(k) application data as well as data for all device product codes. 510(k)s are premarket notifications made to the FDA to demonstrate not only that a device is safe and effective, but also that it is "substantially equivalent" to a device currently on the market. Devices that can claim this substantial equivalence are not subject to the more rigorous Premarket Approval (PMA) process. In a Congressional Hearing regarding the FDA's Medical Device User Fee program, Jeffrey Shuren, Director of the Center for Devices and Radiological Health, testified that while both timelines were becoming shorter, the average time for the FDA to reach a decision regarding a PMA approval was twice as long as that for a 510(k) approval (*Examining FDA*, 2017). As a result, most companies bringing devices to market try to go through the 510(k) process when possible (*Examining FDA*, 2017). My analysis uses 510(k) data because all reprocessed medical devices that have been on the market were approved through the 510(k) rather than PMA processes.

The OpenFDA 510(k) data catalogues all 510(k) applications that were approved between 1976 and December 20, 2019 (Figure 1). Included in this dataset is information about the firm or organization submitting a device for approval, the medical specialty committee who will review the device (cardiovascular, anesthesiology, etc.), a description of the device, the device's K Number (a unique identifier for each application), as well as the device's product code.

I also use the OpenFDA site to download information on device product codes, which are three-digit codes to describe various product classes that devices fall into. For example, all angioscopes for gastroenterological use are listed under product code "LYK". This dataset contains a list of all 6,551 possible device product codes as well as the description for each product code. Each product code is also attached to a medical specialty. Certain product codes are listed specifically as being reprocessed, which allowed for the categorization of devices that I use in the model (Figure 2).

Data Cleaning

I began the analysis by parsing through the product codes dataset to find all devices with "reprocessed" in their description in order to distinguish between devices that were reprocessed

and those that were not. Generally, these device names take the syntax of "Clamp, Vascular, Reprocessed" or "Reprocessed Blood Pressure Cuff", with "Reprocessed" preceding or following the device description. In the dataset, I created a dummy variable that had values of one for all of the devices with "REPROCESSED" in the title and then found the product codes for the original devices which had a matching description. From this, I came up with a list of 57 matched pairs of original devices and their reprocessed versions.

After selecting the product code pairs, one for reprocessed devices and one for their original manufactured counterpart, I merged this dataset with the 510(k) applications, allowing me to compare the number of 510(k) applications for devices from original manufacturers and their reprocessed equivalents by year. I aggregated all of the 510(k) applications by year and originator product code in order to get a summary of how many original devices were brought to market in a certain year and how many reprocessed devices within the matching product code were brought to market in the years prior. It was from here that I could determine the relationship between an innovation by an originator, marked by a 510(k) approval, in year *t* and the number of similar reprocessed devices that were approved by the FDA in periods *t-1*, *t-2*, and *t-3*.

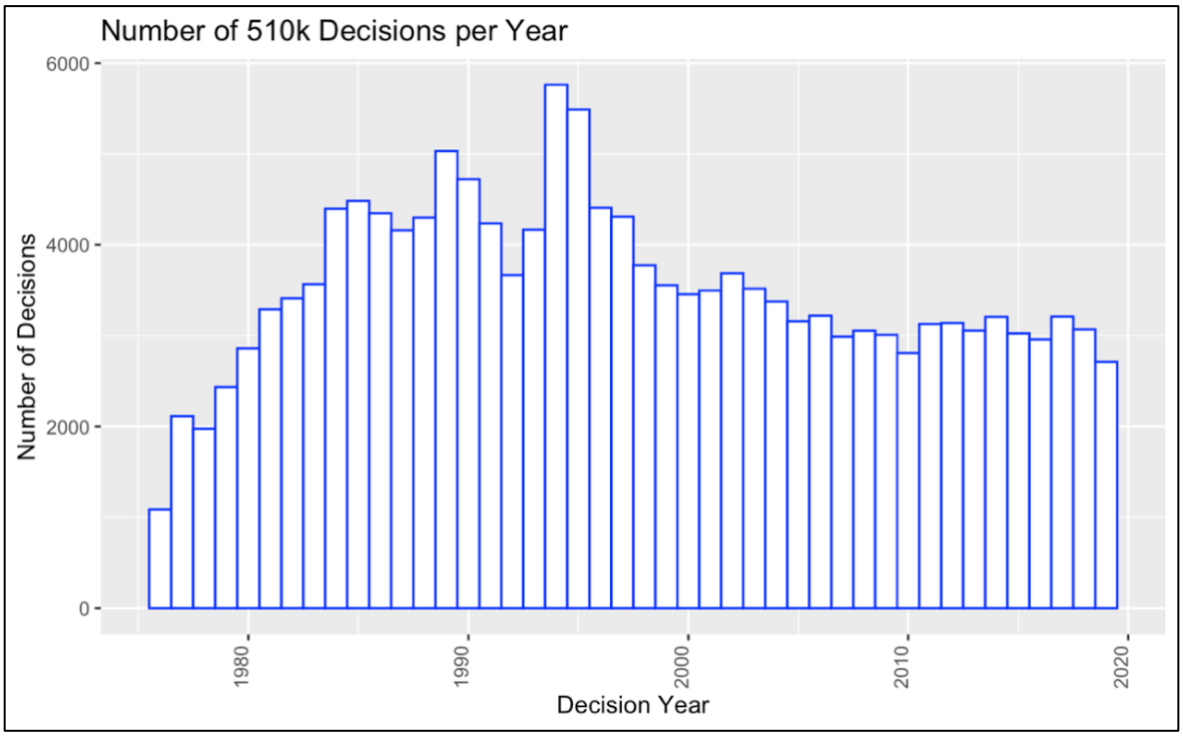
In order to prevent a "zero-truncation" in my data, where aggregating on the independent variable excludes observations that exist only in the dependent variables, I checked to see if there were any reprocessed devices brought to market without an original device being applied for in any of the three years following. I found that there were three devices in the NON product code that were produced in 2005 and three in the NQG product code that were applied for in 2007 which had no counterparts produced by original manufacturers in any of the subsequent three years. I went through and created observations for those values and appended them onto the cleaned dataset, thus removing any concern about the zero-truncation.

Data Limitations

While both datasets provide a comprehensive overview of the history of innovation in the medical device industry, the data provided contains inconsistencies. For example, the names of the manufacturers who submit a 510(k) application are not standardized, meaning that while a company such as 3M might have submitted twenty 510(k) applications in 2015, those twenty applications might fall under the various names and subsidiaries of 3M. In addition, since 1976, there have been a series of changes to the way that medical devices have been categorized as well as the actual reporting restrictions. As a result, product codes have been redefined or added along

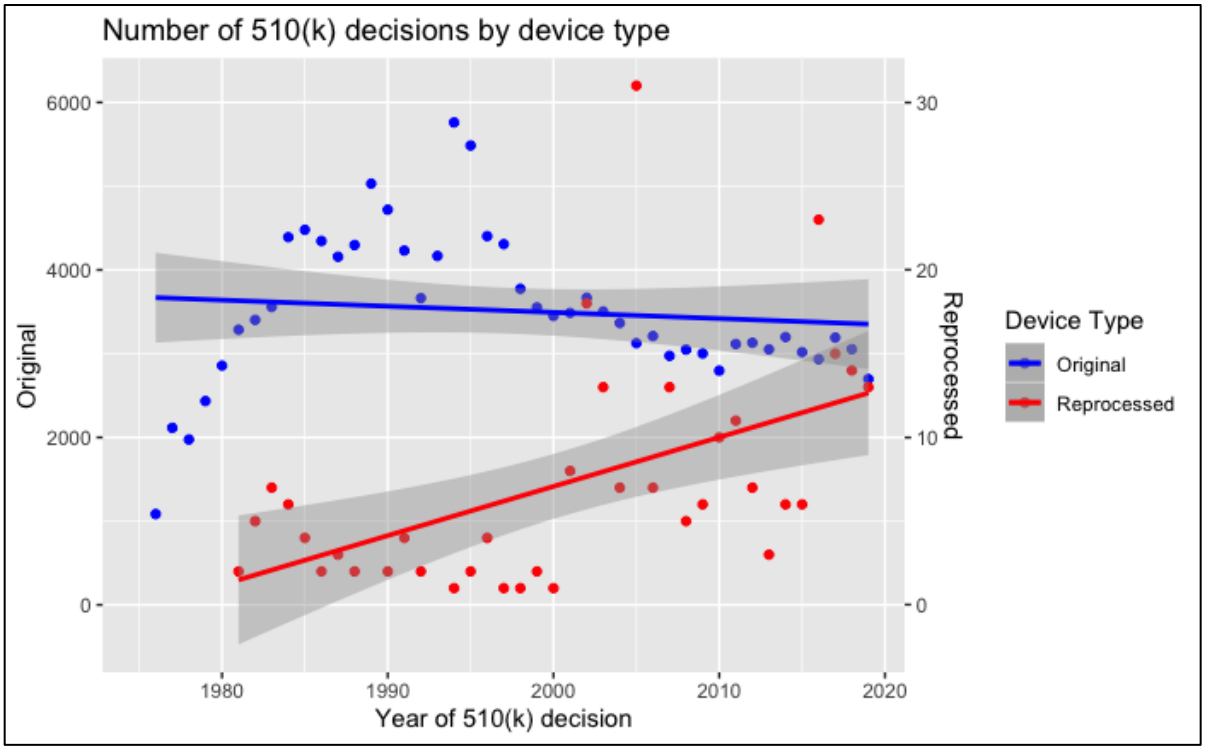
the way, leading to some outliers in the data. While this does not necessarily alter my results as the majority of reprocessed products and product codes have been developed fairly recently, it is still an important consideration in understanding the data and possible outliers.

Figure 1: Total Number of 510(K) Decisions by Year



Source: Author's analysis using FDA data.

Figure 2: Number of 510(k) decisions by device type



Source: Author's analysis using FDA data.

Summary Statistics

Table 1 provides descriptive statistics for medical specialties from the FDA 510(k) application dataset as well as the FDA product code dataset. The table helps to clarify the relationship between the two datasets and, specifically, the connection between medical specialties and the product codes that fall under each one. There are several meaningful points to take from this. The first is the relative sizes of each medical specialty. The three medical specialties with the most product codes, excluding Unknowns, are Gastroenterology & Urology, General & Plastic Surgery, and Clinical Chemistry. However, the specialties with the greatest number of applications were Cardiovascular, Orthopedic, and General Hospital. Those with the greatest number of applications for reprocessed devices were Cardiovascular, Gastroenterology & Urology, and General & Plastic Surgery. These are all significant because there are clear differences between innovation rates within reprocessed and originator devices across different medical specialties, necessitating a control for each specialty. In addition, it's helpful to understand the general trends of innovation for the areas that see more innovation for reprocessed devices.

One additional point of note from Table 1 is the large number of product codes and observations that do not have a listed medical specialty. The most common reason that product codes are not listed under a medical specialty is because the devices are not subject to any form of pre-market approval. In addition, there are null values in the 510(k) dataset because certain devices did not have a relevant product code when applied for and as a result could not be placed into a medical specialty. Both of these groups of values were dropped from the regression analysis.

Table 2 provides a similar summary of product codes and 510(k) applications as Table 1, but splitting the categories by device type, either reprocessed or original. This table clearly illustrates the large gulf in size between the reprocessed device industry and the industry as a whole. As evidenced in Figure 2 and Table 1, while not large, third-party reprocessors are growing at a much faster rate than the rest of the industry and have strong footholds within specific markets. Additionally, Table 2 shows the total number of 510(k) applications without a provided product code. These were also omitted from the analysis.

Table 1: 510(k) applications by medical specialty[3]

Medical Specialty	Abbreviation	(1) Number of product codes	(2) Number of originator observations	(3) Number of reprocessed observations	(5) Mean per year
Anesthesiology	AN	217	7822	0	177.77
Clinical Chemistry	CH	507	12621	0	286.84
Cardiovascular	CV	298	16677	106	381.43
Dental	DE	314	11030	0	250.68
Ear, Nose, & Throat	EN	218	3507	1	79.73
Gastroenterology & Urology	GU	531	9827	32	224.07
Hematology	HE	376	4079	0	92.70
General Hospital	HO	285	13828	0	314.27
Immunology	IM	275	3397	0	77.20
Medical Genetics	MG	5	10	0	2.50
Microbiology	MI	462	6420	0	145.91
Neurology	NE	191	4854	1	110.34
Obstetrics/Gynecology	OB	246	4055	0	92.16
Ophthalmic	OP	292	4440	5	101.02
Orthopedic	OR	246	13958	0	317.23
Pathology	PA	120	289	0	12.04
Physical Medicine	PM	211	5024	0	114.18
Radiology	RA	178	11734	0	266.68
General & Plastic Surgery	SU	511	13378	37	304.89
Clinical Toxicology	TX	265	2920	0	66.36
Unknown	*N/A*	802	3049	22	74.25

Source: Author's analysis using FDA data.
Note: Device 510(k) applications with unknown medical specialties were removed from the regression analysis.

[3] Additional figures are included Appendix A.

Table 2: 510(k) Applications by Device Type

Categorization	(1) Number of product codes	(2) Number of observations	(3) Average per year	(4) SD per year
Original	6474	152919	3475.431	888.68
Reprocessed	76	204	10.737	6.556
N/A	*N/A*	196	5.939	4.085

Source: Author's analysis using FDA data.

Note: Device 510(k) applications without product codes are listed under N/A and were excluded from the regression analysis.

V. Empirical Specification

I estimate the relationship between the number of new originator device applications and the past number of reprocessed device applications while accounting for year and medical specialty using an Ordinary Least Squares model.

$$New_{it} = \beta_{0it} + \beta_1(Reprocess_{i,t-1}) + \beta_2(Reprocess_{i,t-2}) + \beta_3(Reprocess_{i,t-3}) + Year_t + Specialty_i + (Year_t \times Specialty_i) + \varepsilon_{it} \quad (9)$$

In this model, the number of originator applications (New_{it}) in year *t* for devices in medical specialty *i* is a function of the number of applications in years *t-1*, *t-2*, and *t-3* for reprocessed devices in medical specialty *i* ($Reprocess_{i,t-n}$). Year fixed-effects are captured by $Year_t$ and medical specialty fixed-effects are captured by $Specialty_i$. Additionally, an interaction term between $Year_t$ and $Specialty_i$ is included to account for any changes to specific medical specialties in a specific year.

Rather than using a log-transformation in both the predictor and response variables which is customary for models that measure innovation as an elasticity as in Dubois et al. (2015), I chose a linear OLS model due to the large concentration of values close to 0 or 1 for New_{it} as well as $Reprocess_{i,t-1}$, $Reprocess_{i,t-2}$, and $Reprocess_{i,t-3}$. As shown in Table 3, the mean value for New_{it} is 3.859 and the mean value for any of the reprocessed variables is very nearly 0.

Identifications

One concern in this model is that there may be some unobserved factor causing increases in both reprocessed devices and those from originators. However, I don't believe this is the case because it is clear that the overall number of device 510(k) applications has stayed relatively constant since the early 2000s, when reprocessing became more common (Figure 1). Additionally, in an attempt to control for these factors, I use year fixed effects to account for any changes to the medical device industry on a year-by-year basis. Outside of year fixed effects, I assume that the relative costs of innovating as well as any time-invariant differences in innovation between product types can be accounted for by controlling for medical specialty. Finally, I include an interaction term between year and medical specialty to account for any "hot" or "cold" periods, where there may be an exogenous increase in the number of applications for a specific medical specialty in a particular time period.

Another potential issue in this model could be the existence of multicollinearity between the three $Reprocess_{i,t-n}$ variables. Multicollinearity exists when independent variables are correlated with one another, making it hard to determine which predictor variables are influencing movement in the response variable. This can lead to large standard errors and low p-values. To check for any potential multicollinearity, I computer the variance inflation factor (VIF) for the independent variables and found that each variable had values under 1.75.[4] The ideal threshold is for variable inflation factors is under 3, meaning that there is little cause for concern around issues of multicollinearity.

[4] Full VIF values are available in Table 1 of Appendix B.

VI. Results and Discussion

Table 3: Regression Variable Summary Statistics

Linear Model Variables	(1) Number	(2) Mean	(3) SD	(4) Median	(5) Min	(6) Max	(7) SE
New_{it}	38698	3.872	8.109	2	0	816	0.0412
$Reprocess_{i,t-1}$	38698	0.0027	0.0835	0	0	7	0.0004
$Reprocess_{i,t-2}$	38698	0.0025	0.0757	0	0	5	0.0004
$Reprocess_{i,t-3}$	38698	0.0024	0.0729	0	0	5	0.0004

Table 4: Regression Output

Linear Model Variables	(1)	(2)	(3)	(4)	(5)
Intercept	3.829***	1.953***	3.254***	1.454***	1.978†
	(0.0404)	(0.349)	(0.163)	(0.381)	(1.172)
$Reprocess_{i,t-1}$	4.735***	4.680***	4.718***	4.679***	4.765***
	(0.626)	(0.625)	(0.622)	(0.621)	(0.625)
$Reprocess_{i,t-2}$	4.805 ***	4.792***	4.742***	4.768***	4.741***
	(0.6717)	(0.671)	(0.668)	(0.667)	(0.671)
$Reprocess_{i,t-3}$	2.166**	2.149**	2.127**	2.151**	2.268**
	(0.702)	(0.701)	(0.697)	(0.697)	(0.701)
Year Fixed Effects Included?	No	Yes	No	Yes	Yes
Medical Specialty Fixed Effects Included? [5]	No	No	Yes	Yes	Yes
Interaction Term Included?	*N/A*	*N/A*	*N/A*	No	Yes
Adj. R_2	0.00886	0.0139	0.0323	0.0367	0.0392

Note: Standard errors are in parentheses. Significance codes: *** p<0.001, ** p<0.01, * p<0.05, † p<0.1

Table 4 presents the OLS estimation of the effect of the introduction of reprocessed devices on future device applications from originators. The first column shows the output of the basic OLS model with no fixed effects included. The second includes fixed effects just for years, while the

[5] Full year and medical specialty fixed effects coefficients and standard errors are included in Tables 2 and 3 of Appendix B.

third includes fixed effects just for medical specialties. The fourth and fifth models include fixed effects for both years and medical specialties, but only the fifth includes the interaction term between year and medical specialty. I observe statistically significant coefficients for every variable throughout all of the models. The coefficients associated with $Reprocess_{i,t-1}$, $Reprocess_{i,t-2}$, and $Reprocess_{i,t-3}$ represent the effect that an additional 510(k) application from a reprocessor has on the number of 510(k)s that will be applied for by originators 1, 2, and 3 years later. From this, the direction and magnitude of an effect can be determined.

As displayed in column 5 of Table 4, when including both fixed effects and an interaction term, the coefficients for $Reprocess_{i,t-1}$ and $Reprocess_{i,t-2}$ are statistically significant to a 0.001 level and the coefficient for $Reprocess_{i,t-3}$ is significant to a 0.01 level. Thus, I find a significant relationship between an increase in the number of reprocessed devices coming to market within a specific product class in years *t-1*, *t-2*, and *t-3*, and the number of devices produced by originators in the corresponding originator product class in year *t*. Specifically, reprocessed devices in *t-1* and *t-2* have the strongest correlation with the creation of new devices in *t*. This time pattern corroborates the intuition that there will be a slight lag in the increase of original products to account for the development and FDA approval of a new single-use device from an originator (Emergo Group, 2017).

While the R^2 values of each subsequent model appear to increase, meaning that each is slightly more predictive of the relationship between the independent and dependent variables, the models used in this study still have low predictive values. This means that while the number of reprocessed device applications still provides distinct information about the number of future device applications from originators, the datapoints fall far from the regression line, producing high residual values. One potential explanation for this is the limited number of reprocessed devices that have been brought to market relative to the number of original devices. This results in a large number of observations in the data with no related reprocessed devices being produced in the years preceding. When selecting only the observations that have a non-zero value for *t-1*, *t-2*, or *t-3*, the R^2 value naturally increases to 0.59.

Placing these results in the context of the industry overall, the analysis depicts a substantial increase in original device applications given the entry of a reprocessed device. Based on model 5, an additional 510(k) from a reprocessor results in an expected increase in 510(k) applications from originators within a corresponding product code of 4.765 after one year, 4.741 after two

years, and 2.268 after three years. As seen in Table 3, the mean number of 510(k) applications from originators in each year-product code pair is 3.872. The increase is relatively large.

These results in many ways corroborate the findings of Greenstein and Ramey (1998) and Chen and Schwartz (2013), supporting the conclusion that the introduction of a competitor leads to increased innovation relative to either perfect competition or a monopoly. Although my work does not explicitly analyze the competitive landscape before the entry of reprocessors, the fact that reprocessors can have such a drastic impact on innovation rates might imply that the medical device industry more resembles a monopoly than perfect competition. Regardless, there is more innovation given the entry of a reprocessed device than in the original market conditions. With regards to literature on remanufacturing, though it is unclear whether or not the innovations are increasing the marginal cost of reprocessing a device as was theorized by Majumder and Groenevelt (2009), reports of the inclusion of kill switches in new iterations of original devices suggests that this increase in innovation in some way makes reprocessing more difficult (Chamoff, 2015). These findings also show that not all industries respond to competition in the same way. My results counter the outcomes of the empirical analysis conducted by Autor et al. (2016) regarding the effects of an increase in competition from Chinese manufacturers on domestic manufacturing.

Limitations and Future Research

As this is the first paper studying remanufacturing in the medical device industry, there are several limitations in my study design that can be modified for future research. Potential adjustments to the methodology used in this paper include the aggregation of 510(k) observations by firm, product code, and year, rather than just by product code and year. Doing so would allow researchers to control for any unobserved fluctuations occurring at a firm level. There is also the question of exactly what "innovative" means. While a company might be considered to be "innovating" because they apply for more 510(k)s, it is unclear what the value to society is of each additional 510(k). A framework for determining the actual benefits of a new technology is provided by Dranove et al. (2014) in their study of the pharmaceutical industry, where new drugs are categorized by the social value of their introduction. Additionally, incorporating an analysis of market concentration both before and after the introduction of reprocessed devices would provide a clearer understanding of the actual threat that reprocessors pose to originators. However, this would require proprietary sales and pricing data from different manufacturers which may be

difficult to find. Beyond the constraints of this model, it might also be worthwhile to pursue a difference-in-differences model to determine how application rates for any device that is "reprocessable" have shifted following the growth of the reprocessing industry. However, this requires a clear understanding of the breadth of all medical devices that can be commercially reprocessed in order to understand how the market for "reprocessable" devices has changed relative to "unreprocessable" devices.

VII. Conclusion

In an effort to understand the effects of the entry of third party "reprocessors" of single-use medical devices on innovation within the medical device industry, I look at the rates of 510(k) applications for reprocessed and original devices over time. When controlling for year and medical specialty fixed effects, I come to the conclusion that there is a statistically significant relationship between the number of devices brought to market by reprocessors and the number of new devices developed by originators in that market segment in the years following, with the greatest effect occurs one and two years after the entrance of a new reprocessed device. Originators will bring to market almost five more devices of a specific product code given the introduction of one additional reprocessed device of that type in either of the two years before.

The implications of these findings are that when faced with price competition from a remanufacturer, original manufacturers in this industry respond by innovating and bringing new devices to market. This supports theoretical evidence that the entry of a competitor in a market with imperfect competition can effectively catalyze innovation, as was determined by Chen and Schwartz (2013). However, my analysis contradicts the outcomes of an empirical study by Autor et al. (2016), which determined that an increase in competition from foreign manufacturers stifled domestic innovation. While my results provide strong insight into the effects of increased competition on innovation within the context of medical device market, the dearth of literature in the field leaves room for the continuation of future research.

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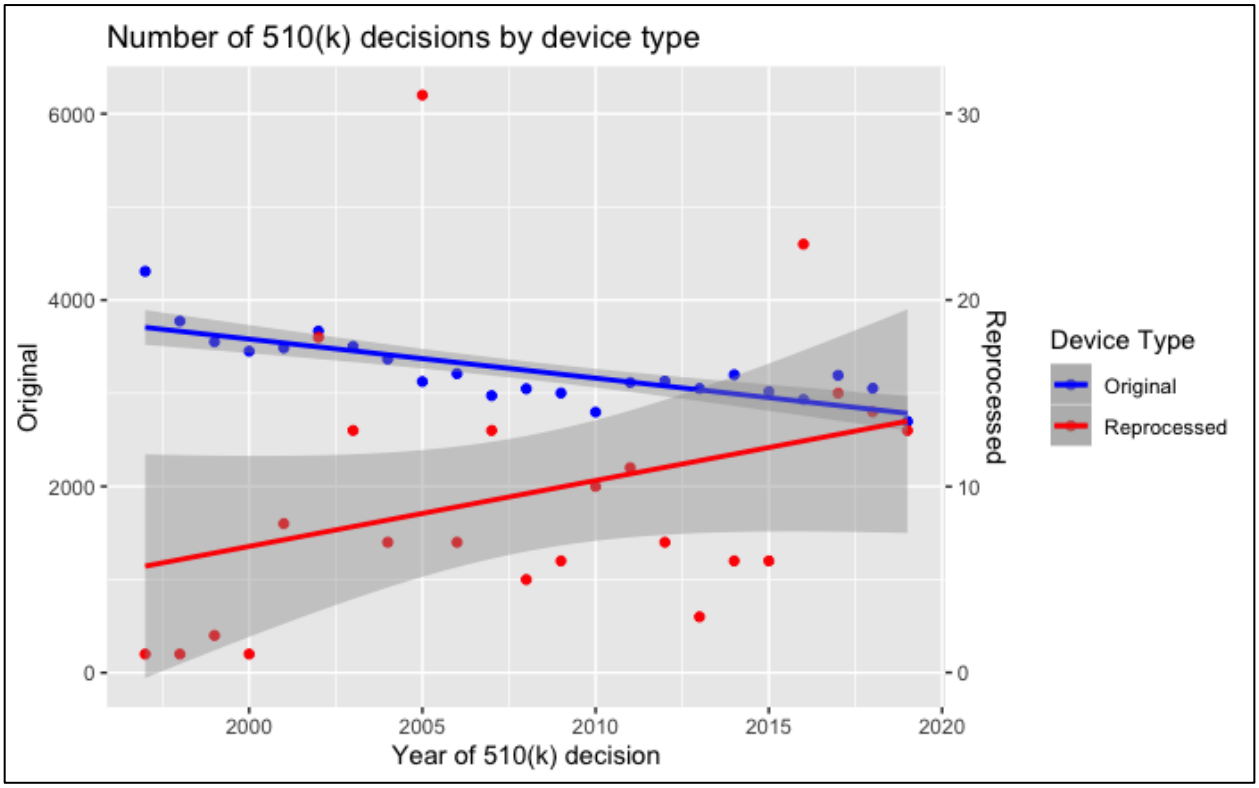
Appendix A

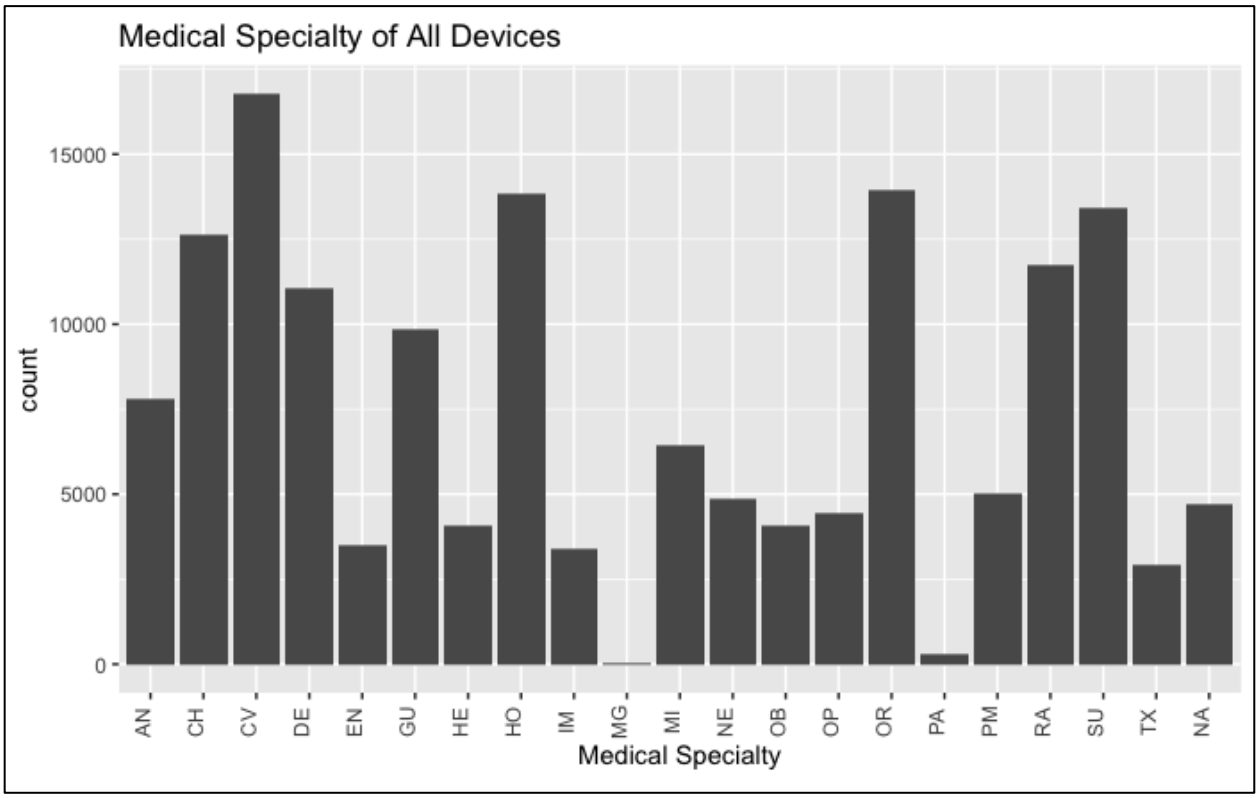
Figure A1: Number of 510(k) decisions by device type, Post 2000



Source: Author's analysis using FDA data.

There is an increase in the number of new device applications for reprocessed devices as compared to original devices over time.

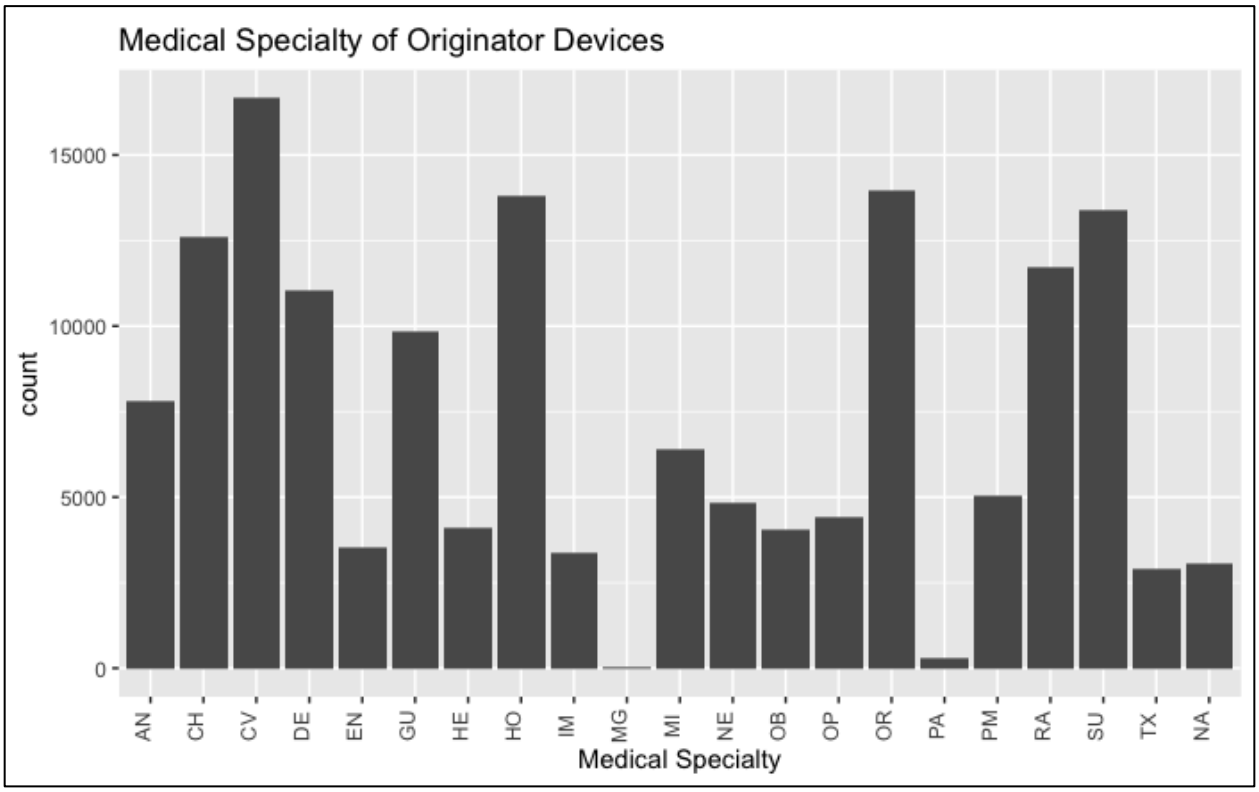
Figure A2: Number of 510(k) applications by medical specialty, All



Source: Author's analysis using FDA data.

There are large disparities in the number of 510(k) applications for all devices by medical specialty review committee.

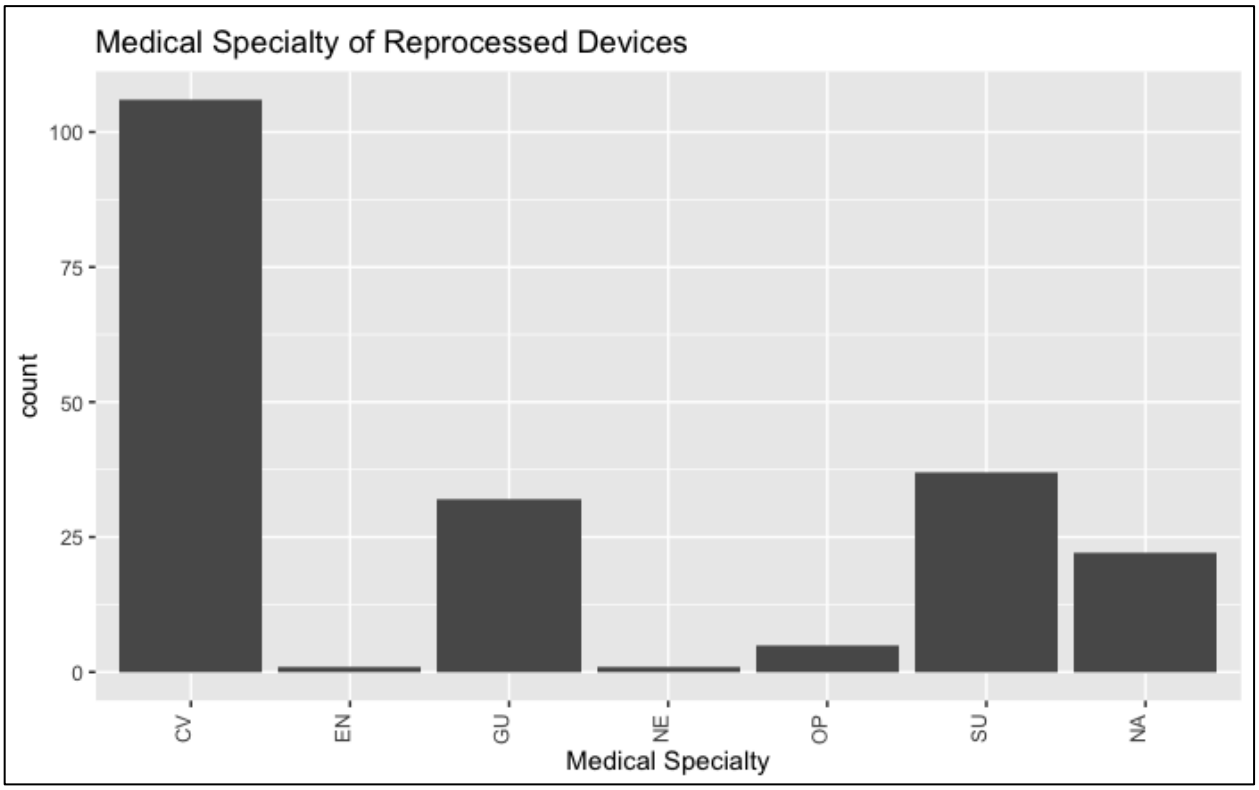
Figure A3: Number of 510(k) applications by medical specialty, Originator only



Source: Author's analysis using FDA data.

There are large disparities in the number of 510(k) applications for devices from original equipment manufacturers by medical specialty review committee.

Figure A4: Number of 510(k) applications by medical specialty, Reprocessed only



Source: Author's analysis using FDA data.

There are large disparities in the number of 510(k) applications for devices from reprocessors by medical specialty review committee.

Appendix B

Table B1: Variance Inflation Factor calculations

Variable	GVIF	Degrees of Freedom	$GVIF^{\frac{1}{2*df}}$
$Reprocess_{i,t-1}$	1.643894	1	1.282144
$Reprocess_{i,t-2}$	1.557644	1	1.248056
$Reprocess_{i,t-3}$	1.576534	1	1.255601
Year Fixed Effects	1.075555	43	1.000847
Medical Specialty Fixed Effects	1.071646	19	1.001823

Note: Concerns about multicollinearity are raised when Generalized VIF scores exceed 3.

Table B2: Fixed effects by year in each model

Year	(2)	(4)	(5)	Year	(2)	(4)	(5)
1977	0.464	0.517	0.106	1999	2.246***	2.252***	1.314
	(0.445)	(0.444)	(1.563)		(0.445)	(0.446)	(1.707)
1978	0.301	0.301	0.310	2000	2.481***	2.479***	1.043
	(0.444)	(0.444)	(1.563)		(0.452)	(0.453)	(1.657)
1979	0.752†	0.813†	1.129	2001	2.361***	2.354***	0.784
	(0.441)	(0.441)	(1.532)		(0.449)	(0.450)	(1.696)
1980	0.930*	0.973*	0.619	2002	2.459***	2.420***	1.627
	(0.4340	(0.434)	(1.522)		(0.447)	(0.448)	(1.742)
1981	1.081*	1.154**	1.272	2003	2.362***	2.323***	1.044
	(0.427)	(0.427)	(1.517)		(0.450)	(0.451)	(1.676)
1982	1.086*	1.176**	0.988	2004	2.065***	1.981***	2.065
	(0.427)	(0.428)	(1.563)		(0.447)	(0.448)	(1.657)
1983	1.170**	1.281**	1.130	2005	2.030***	1.930***	1.334
	(0.426)	(0.426)	(1.492)		(0.453)	(0.455)	(1.640)
1984	1.538***	1.618***	1.994	2006	2.050***	1.944***	1.097
	(0.419)	(0.419)	(1.496)		(0.452)	(0.454)	(1.718)
1985	1.789***	1.825***	1.307	2007	1.783***	1.576***	1.260
	(0.422)	(0.423)	(1.458)		(0.453)	(0.454)	(1.696)
1986	1.705***	1.711***	1.968	2008	2.002***	1.795***	1.719
	(0.422)	(0.422)	(1.492)		(0.457)	(0.458)	(1.686)
1987	1.570***	1.565***	1.810	2009	2.005***	1.803***	1.254
	(0.421)	(0.421)	(1.527)		(0.457)	(0.459)	(1.686)
1988	1.860***	1.926***	1.822	2010	1.927***	1.765***	0.674
	(0.423)	(0.423)	(1.509)		(0.461)	(0.463)	(1.657)
1989	2.344***	2.361***	1.675	2011	2.121***	1.904***	0.981
	(0.421)	(0.421)	(1.489)		(0.455)	(0.456)	(1.632)
1990	2.147***	2.154***	2.261	2012	2.189***	1.990***	1.574
	(0.422)	(0.422)	(1.504)		(0.457)	(0.459)	(1.742)
1991	1.963***	1.954***	1.457	2013	1.924***	1.745***	0.672
	(0.426)	(0.427)	(1.513)		(0.453)	(0.455)	(1.718)
1992	1.722***	1.688***	1.052	2014	2.210***	2.037***	0.973
	(0.432)	(0.433)	(1.522)		(0.455)	(0.458)	(1.707)
1993	2.170***	2.100***	2.275	2015	2.233***	2.025***	0.404
	(0.431)	(0.431)	(1.489)		(0.460)	(0.463)	(1.798)
1994	3.039***	2.973***	2.037	2016	1.969***	1.778***	0.181
	(0.421)	(0.422)	(1.536)		(0.456)	(0.458)	(1.676)
1995	3.085***	3.087***	2.346	2017	2.000***	1.836***	0.069
	(0.425)	(0.426)	(1.504)		(0.450)	(0.452)	(1.696)
1996	2.406***	2.423***	1.635	2018	1.975**	1.819***	0.260
	(0.431)	(0.432)	(1.547)		(0.455)	(0.457)	(1.696)
1997	2.377***	2.395***	1.108	2019	1.780***	1.541***	0.355
	(0.432)	(0.433)	(1.569)		(0.463)	(0.465)	(1.865)
1998	2.367***	2.368***	1.675				
	(0.442)	(0.444)	(1.632)				

Note: 1976 serves as the base year. Standard errors are in parentheses.
Significance codes: *** p<0.001, ** p<0.01, * p<0.05, † p<0.1

Table B3: Fixed effects by medical specialty in each model

Medical Specialty	(3)	(4)	(5)
Clinical Chemistry	-0.033	0.003	0.088
	(0.207)	(0.206)	(1.489)
Cardiovascular	1.417***	1.368***	0.705
	(0.212)	(0.212)	(1.707)
Dental	1.012***	0.992***	-0.198
	(0.226)	(0.226)	(1.707)
Ear, Nose, & Throat	0.438	0.407	0.272
	(0.306)	(0.305)	(3.045)
Gastroenterology & Urology	-0.352	-0.452*	0.150
	(0.214)	(0.214)	(1.730)
Hematology	-0.627*	-0.583*	-0.597
	(0.260)	(0.259)	(2.093)
General Hospital	2.449***	2.424***	-0.048
	(0.230)	(0.229)	(1.686)
Immunology	-1.025***	-1.082***	-0.478
	(0.261)	(0.261)	(2.210)
Medical Genetics	-2.143	-2.099	-0.833
	(2.664)	(2.663)	(5.805)
Microbiology	-0.124	-0.136	-0.478
	(0.240)	(0.239)	(2.002)
Neurology	-0.306	-0.411	-0.478
	(0.255)	(0.256)	(2.577)
Obstetrics/Gynecology	-0.353	-0.477†	-0.363
	(0.268)	(0.268)	(2.497)
Opthalmic	-0.155	-0.210	-0.449
	(0.266)	(0.266)	(2.256)
Orthopedic	3.260***	3.174***	-0.096
	(0.237)	(0.237)	(2.256)
Pathology	-1.733**	-1.316*	-0.835
	(0.601)	(0.602)	(3.225)
Physical Medicine	0.100	0.169	0.711
	(0.263)	(0.262)	(1.885)
Radiology	3.324***	3.228***	-0.445
	(0.249)	(0.249)	(2.363)
General & Plastic Surgery	0.857***	0.826***	0.158
	(0.216)	(0.216)	(1.676)
Clinical Toxicology	-0.960***	-1.003***	-0.796
	(0.277)	(0.276)	(2.668)

Note: Anesthesiology serves as the base medical specialty. Standard errors are in parentheses.
Significance codes: *** p<0.001, ** p<0.01, * p<0.05, † p<0.1