Making a Comprehensive Inventory of Medical Devices Marketed in the U.S.

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Introduction

A well-organized, query-ready database of medical devices would be a useful tool to many researchers as it would show meaningful trends that provide more information about the full therapeutic landscape of specific diseases. Such a database may also support exploratory research into new therapeutic cases for existing devices. In order to create this database, the goal of this project is to compile all of the devices in the FDA's datasets into a more accessible format.

Approval Process

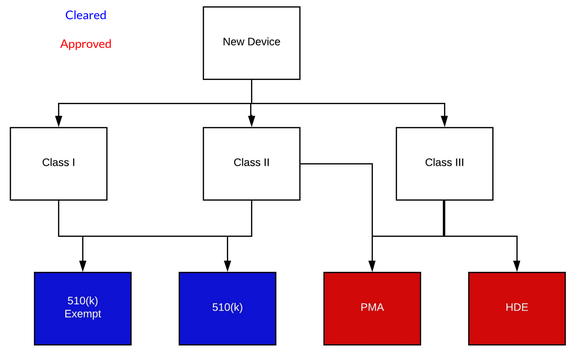

Figure 1: This is the FDA's general authorization process that all new devices have to go through. When a new device is made, it is classified as Class I, II, or III, the device then goes through an assigned authorization process. Class I and II typically go through either 510(k) or are 510(k) exempt if they are substantially equivalent to a previously marketed device, while Class III generally goes through PMA or HDE. Only the devices that go through PMA or HDE are "FDA Approved" while the rest are "FDA Cleared".

Databases

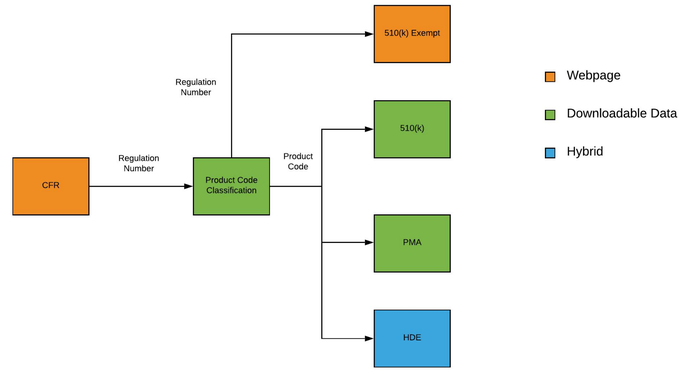

Figure 2: These are the datasets accessed and analyzed. Both the CFR and 510(k) Exempt sets were web pages that required Javascripts to extract, while the Product Code, 510(k), and PMA sets were easily downloadable. The HDE dataset only downloaded some of the data while the rest require a Javascript script. Both the Product Code and 510(k) Exempt data used Regulation Numbers found in the CFR, while the 510(k), PMA, and HDE data used Product Codes found in the CFR.

Analysis

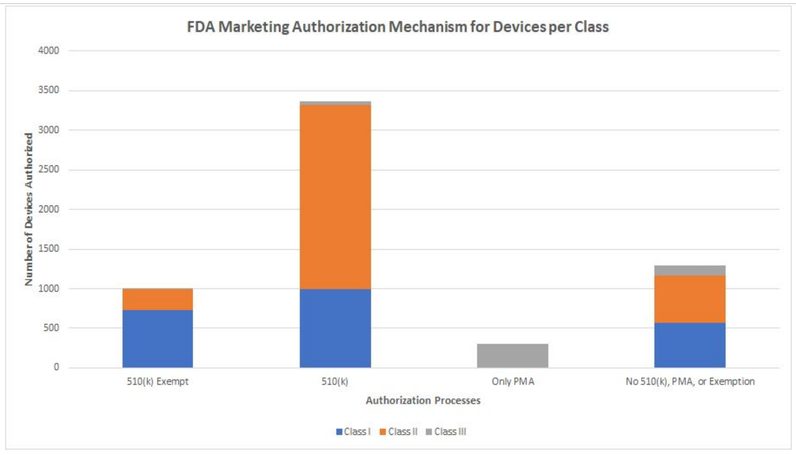

Figure 3: The bar graph shows the number of devices and their class that went through each of the listed market authorization processes. If a device used multiple authorization processes, it was only listed under its least stringent process. There were also product codes for which no specific authorization event was discovered, as these may have been first authorized prior to the formation of the datasets, or may have been approved under HDE.

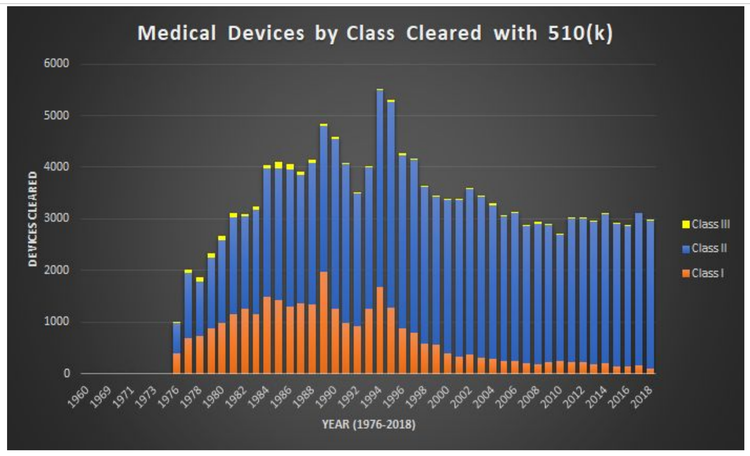

Figure 4: This chart shows the number of unique 510(k) applications cleared by the FDA from 1960-2018. As these are the number of unique applications, a device was counted multiple times if multiple companies made and applied for the same device. Although this process mostly involves Class I and II, some Class III devices were approved by this process.

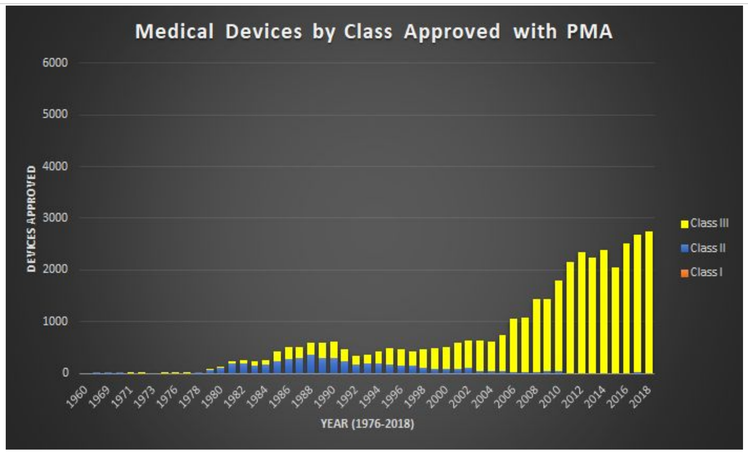

Figure 5: This chart shows the number of unique PMA applications approved by the FDA from 1960-2018. Like Figure 4, a device was counted multiple times if multiple companies submitted an application for the same device. Although very rare, Class I devices do appear and mostly consist of about one device in some of the years, which is why they are unnoticeable in the chart.

Observations and Possible Conclusions

- 510(k) Class III devices
  - Could be part of Class I or II devices or were reclassified
- PMA Class I and II devices
  - Could be part of Class III devices or were the first times they were ever introduced
- Decrease in 510(k) due to more exemptions
- Increase in PMA and decrease in 510(k) show new devices are still going strict approval processes

Future Direction

- Extract data from remaining databases
  - HDE, De Novo, MAUDE, MedSun, CLIA
- Deep dive into existing data for explanations about authorization processes
- Match devices to diseases and ailments they can treat
- Inxight: Medical Devices

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