IMPLANTABLE MEDICAL DEVICES

EXPLORATORY DATA ANALYSIS

An analysis of the American Database for Medical Implant Transparency (ADMIT).

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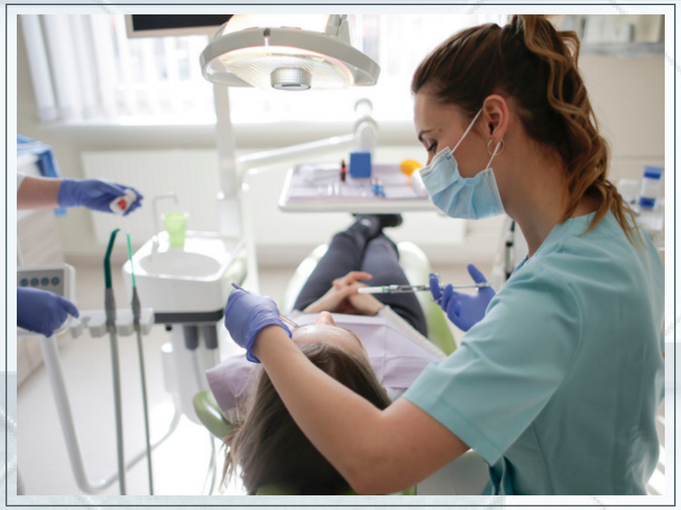
Python Project

AGENDA

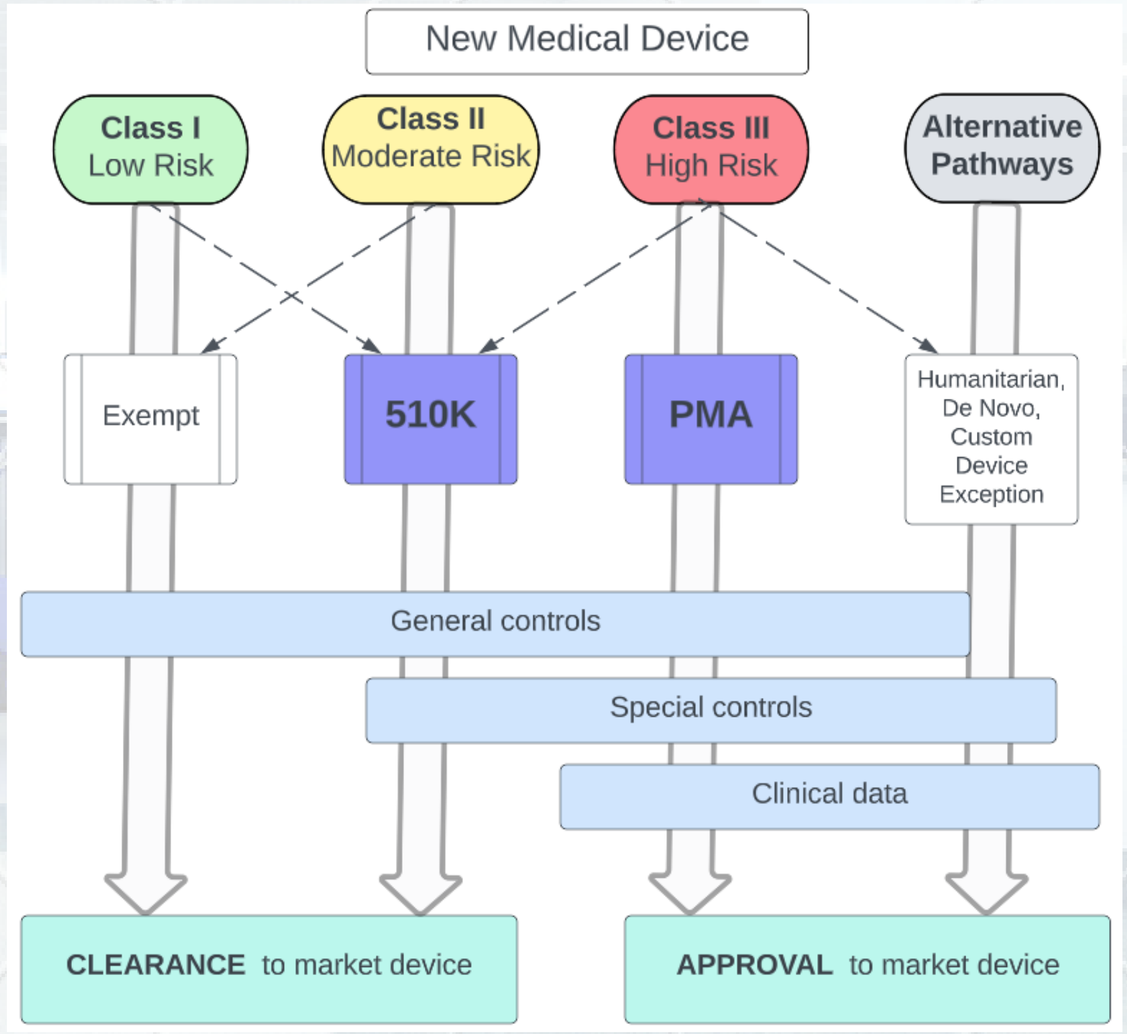
1. Background
2. Data Overview
3. Questions of Interest
4. Analysis
5. Summary
6. Future work

IMPLANTABLE MEDICAL DEVICES

- Medical implants are devices or tissues that are placed inside or on the surface of the body.
- Roughly **32 million Americans**, about **10 percent**, have an implanted medical device in them.
- The global implantable medical devices market was valued at **$92 billion** in 2020.



FDA Regulatory Pathways for Medical Devices



PROBLEMS

- Medical devices have been linked to more than **80,000 deaths** and **1.7 million** injuries in the last decade.
- The FDA collects data voluntarily from manufacturers, doctors, and patients, often leading to incomplete reporting.

DATA SUMMARY

- American Database for Medical Implant Transparency (ADMIT) from Harvard Dataverse
- **319,948 observations** of different medical device products
- **21 features**

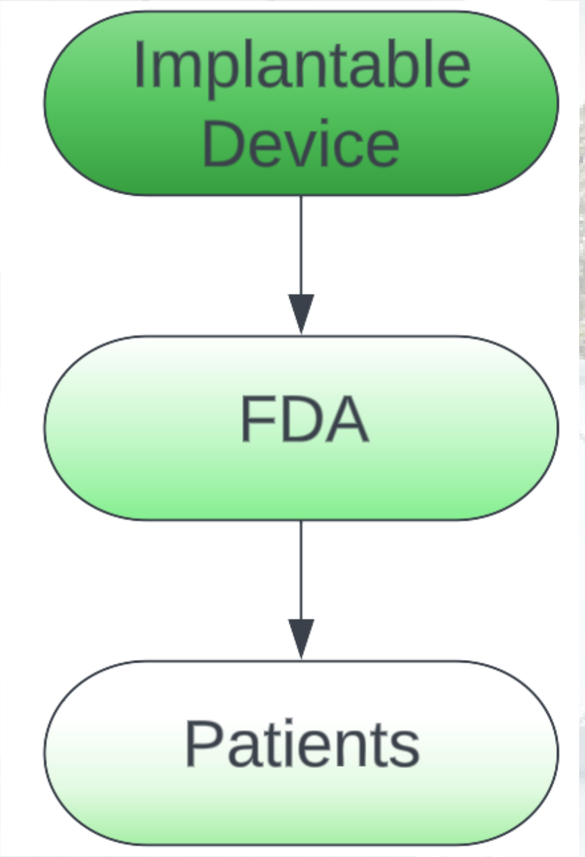
Features:			
company_name	brand_name	product_code	model_number
med_specialty	device_gender	**premarket_submissions_number**	**device_class**
recall	**malfunction**	**injury**	**death**
totalAE	**has_clinicalTrial**	**Study Sponsor**	n
nwomen	rwomen	**c_SeriousAE**	**c_OtherAE**
c_TotalAE			

QUESTIONS OF INTEREST

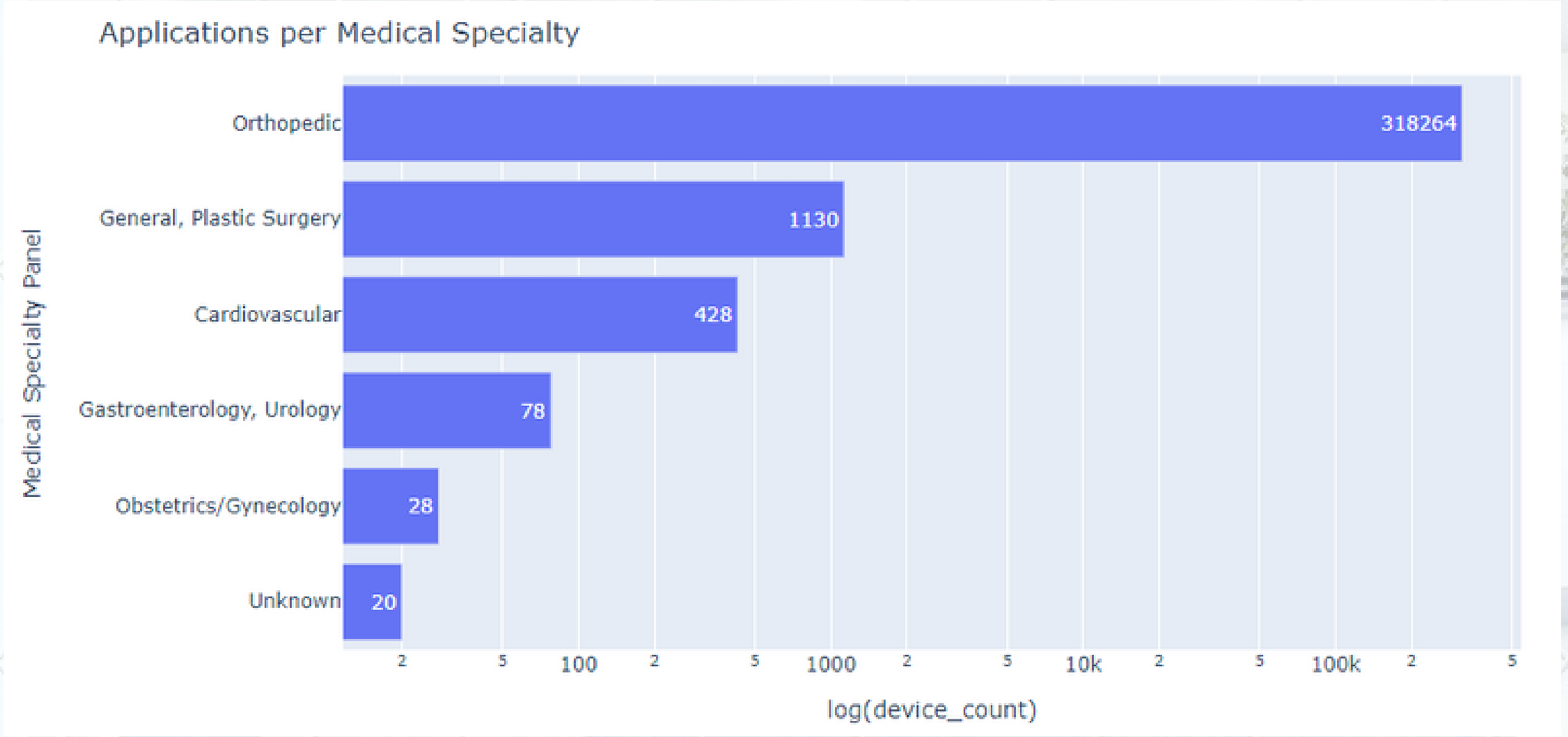
1. Implantable Devices
    a. What companies produce the most devices?
    b. What medical industry do they target?

2. FDA
    a. How does the FDA classify these devices?
    b. What FDA panel reviews the most implantable medical device applications?

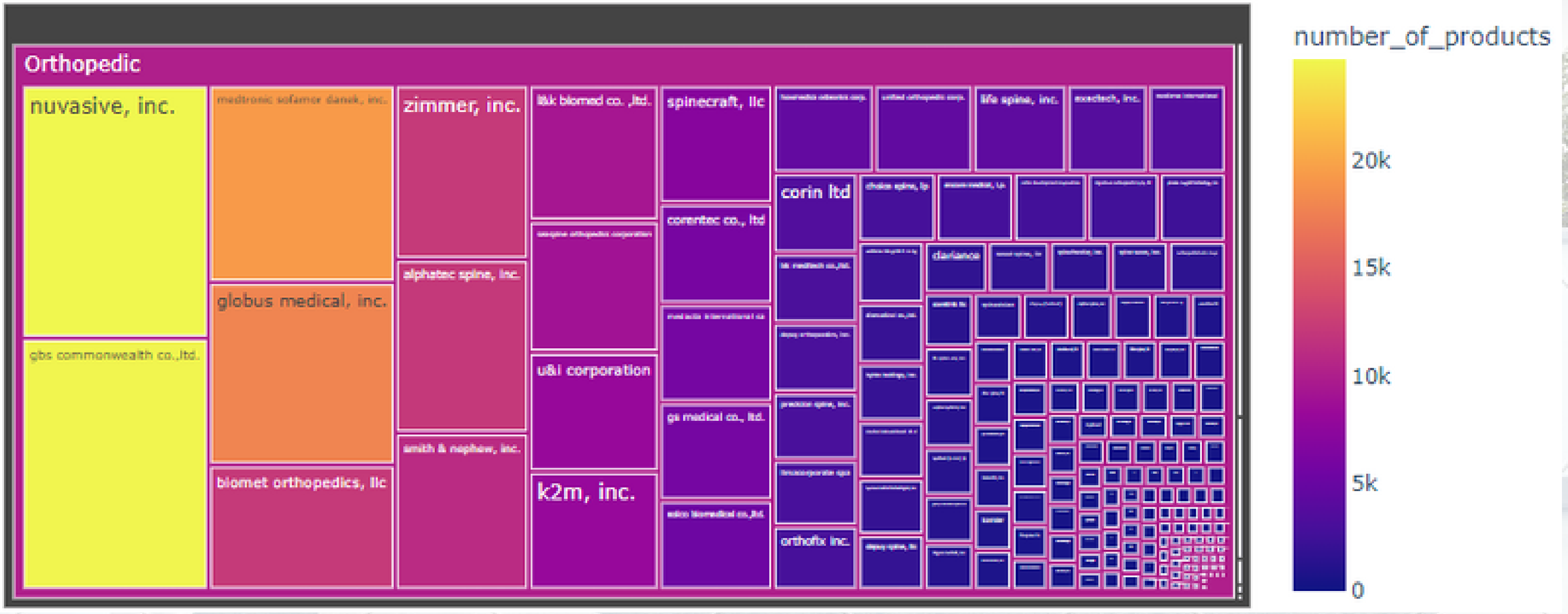
3. Patients
    a. What device class has the most recalls, malfunctions, injuries, deaths, and adverse events reported?



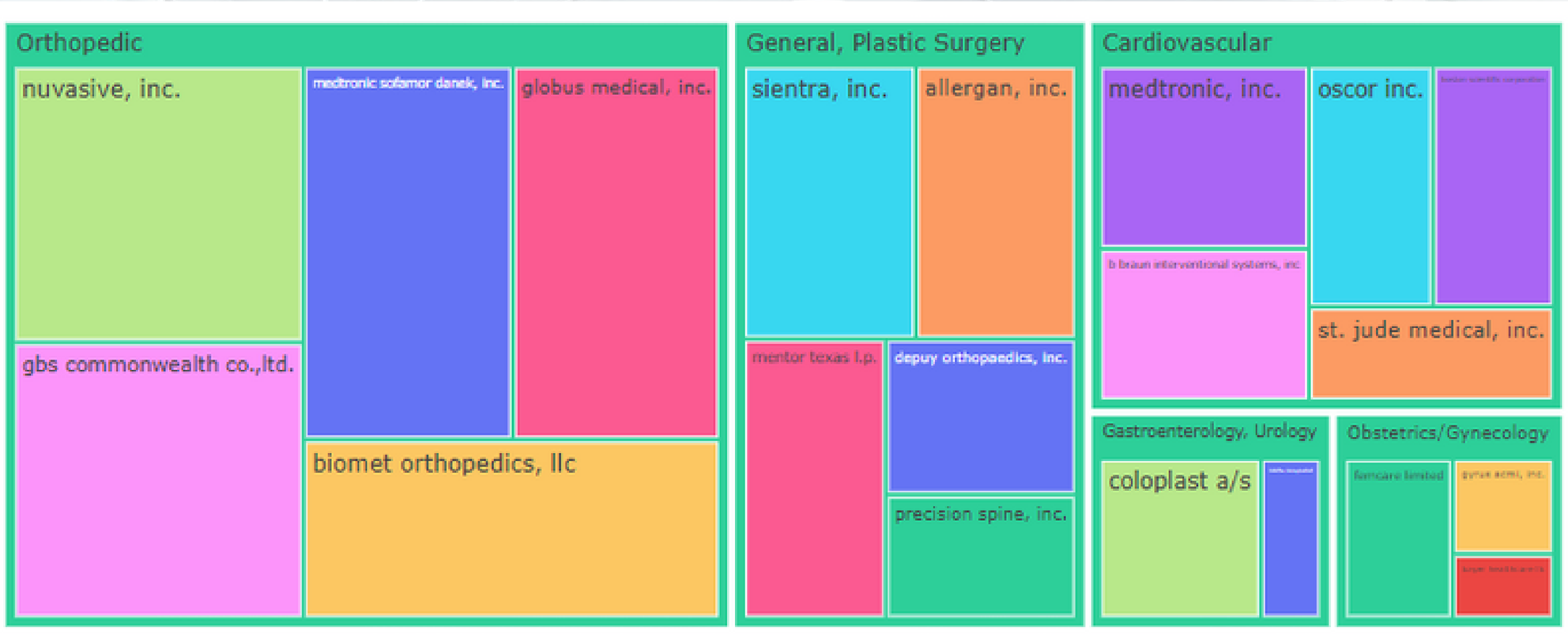
Applications per Medical Specialty



Major Producers of Implantable Medical Devices

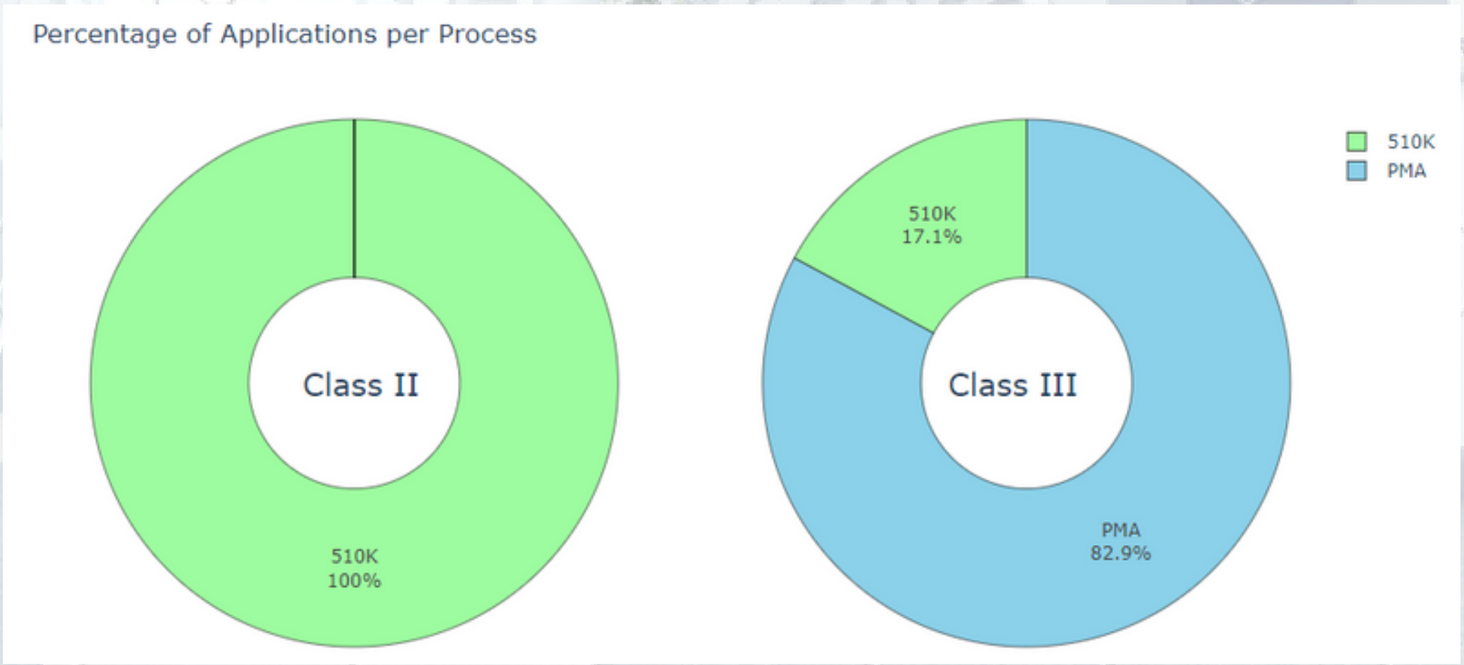


Major Producers of Implantable Medical Devices per Specialty (log scaled)

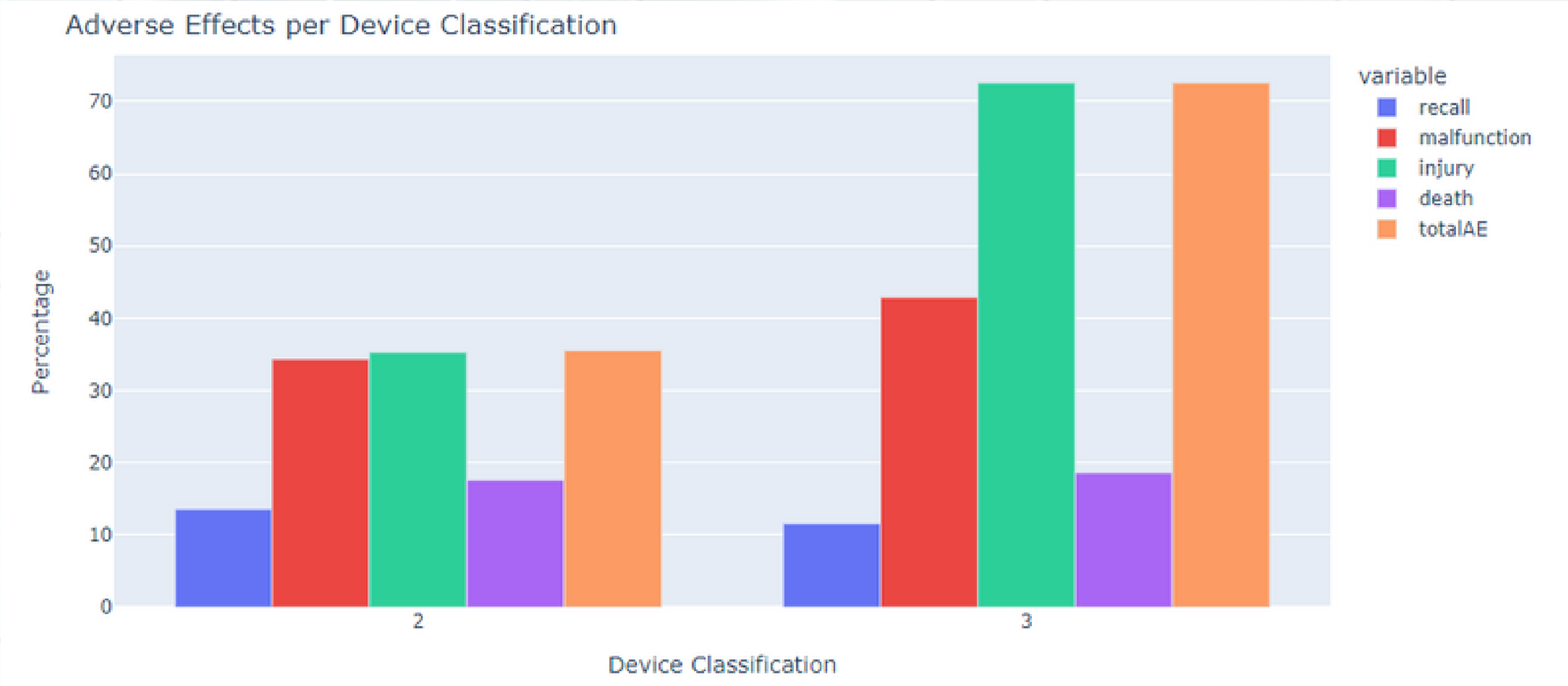


Percentage of Applications per Process

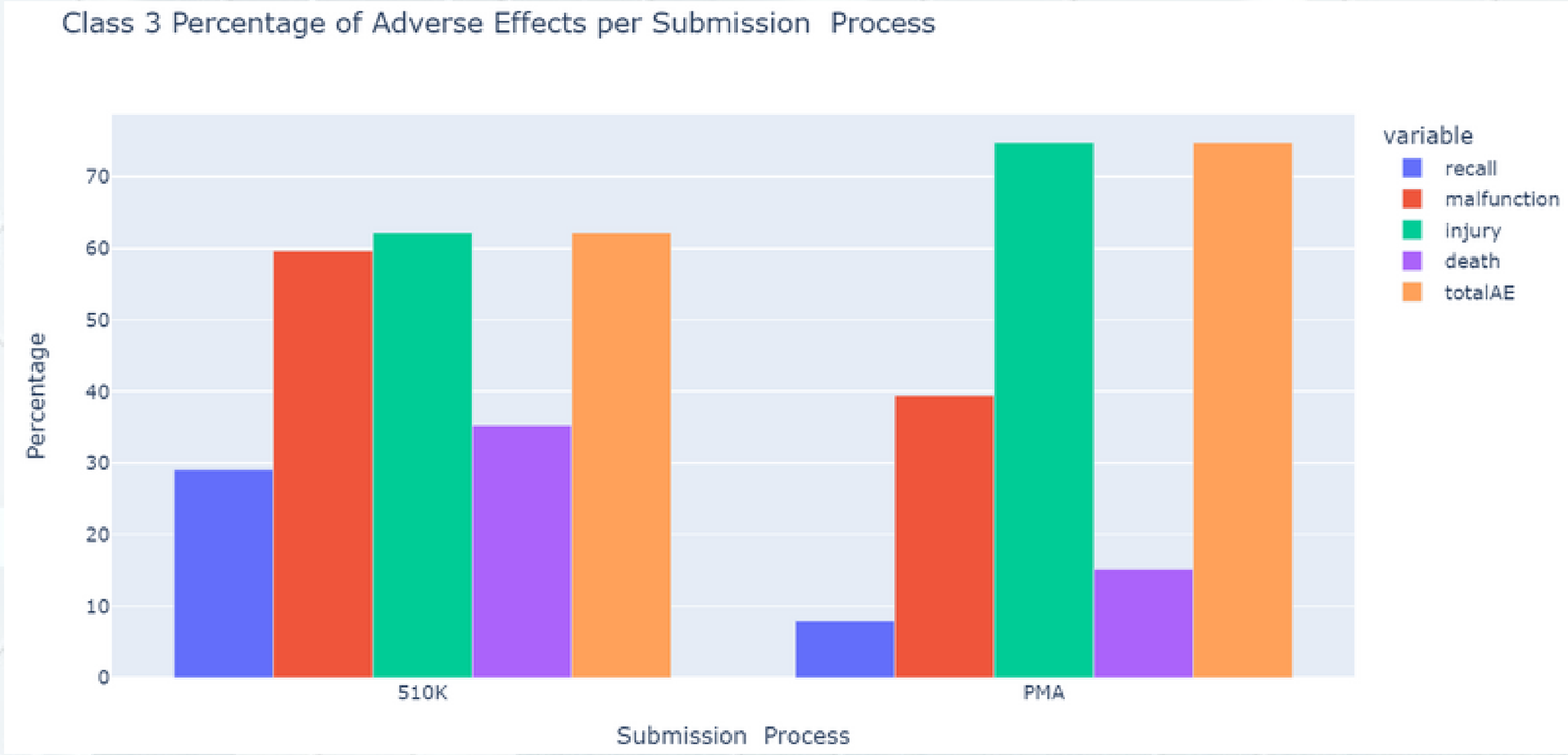
	device_class	submit_process	num_of_applications	percentage
0	2	510K	318340	100.00
3	2	PMA	2	0.00
2	3	510K	275	17.12
1	3	PMA	1331	82.88



Adverse Effects per Device Classification



Class 3 Percentage of Adverse Effects per Submission Process



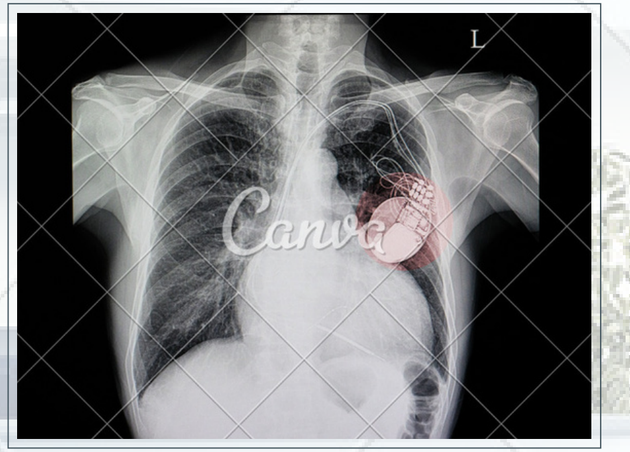
What percentage of clinical trials are sponsored by the manufacturer of the device?

has_clinicalTrial	submit_process	has_clinicalTrial	Study Sponsor	Percentage
Y	PMA	842	842	100.0

A closer look at the data shows that some devices have more adverse effects than others. For **2.93% of devices** for which medical trial data was available, **100% of patients reported adverse effects.**

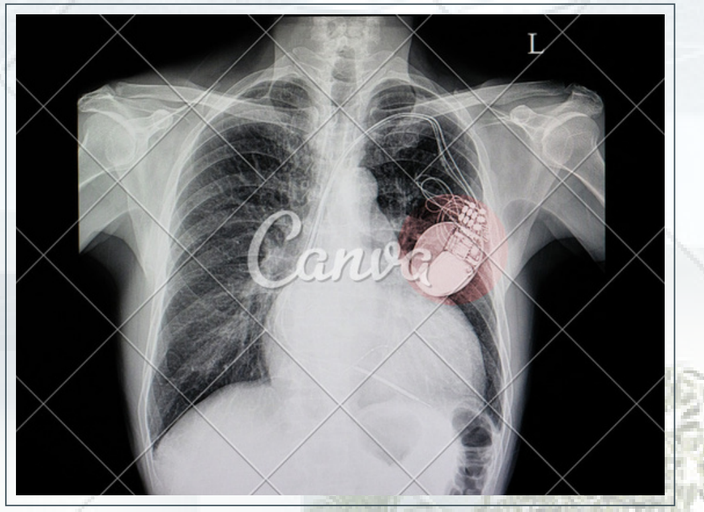
SUMMARY

- Over 99% of implantable devices target the Orthopedics sector
- Nuvasive and GBS Commonwealth are the major manufacturers.
- The FDA classifies medical devices into Class 1 (low risk), Class 2 (moderate risk), or Class 3 (high risk).
- Most implantable devices are classified as Class 2, therefore, obtained FDA clearance through a 510k application.
- 17.1% of Class 3 devices went through a 510k application, while 82.9% followed the PMA route.
- Class 3 devices led to a higher rate of malfunctions, injuries, deaths, and general total adverse effects.
- 2.93% of devices had 100% of patients that reported adverse effects during clinical trials.
- FDA should implement a formal process to collect data about negative side effects.



FUTURE WORK

- Can the specific requirements for the PMA hint at why the PMA process leads to more injuries?
- Can we predict what would happen if all Class 3 high-risk devices file a PMA instead of a 510k application? How would the adverse effect change?
- Can we obtain more specific data on what each product does and associate its function with the adverse effect reported?
- Is there a correlation between clinical trials and total adverse events reported?




ANY QUESTIONS