Innovation in AI for the Surgical Patient: An Analysis of FDA approved AI/ML Medical Devices

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FDA defines artificial intelligence (AI) & machine learning (ML) as…

A machine-driven system that uses human-defined goals to make predictions, recommendations, or decisions

How does the FDA approve medical devices?

FDA classifies devices based on the risk they pose to patients

Class I → lowest risk
Class II → moderate risk
Class III → highest risk

Class II & III devices must undergo a higher standard of testing before approval

What is this approval process?

Option 1: Premarket Approval (PMA)

- *The **most** rigorous approval pathway*
- *Can consist of quality assurance inspections, clinical & non-clinical studies*
- *Applies to Class III devices*

Option 2: 510(k) Clearance

- *The **least** rigorous approval pathway*
- *The device is demonstrated to be "substantially equivalent" to a previously approved device*
- *Applies to Class II devices*

Research Question

What is the current state of FDA-approved AI/ML enabled medical devices in surgery?

Methods

Data was collected from all published records of FDA-approved AI/ML devices as of March 8th, 2024

Devices included covered any of the following:

- *Aid surgical planning*
- *Detect operative lesions/complications in real time*
- *Are involved intra-operatively*

Results *(as of March 2024)*

Total AI/ML Devices Approved → 692

Surgically Applicable Devices → 535

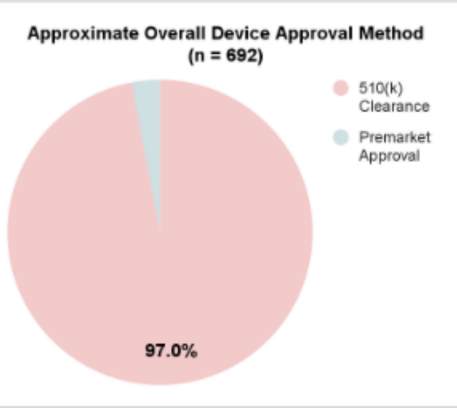
Devices Used in Operative Management → 35

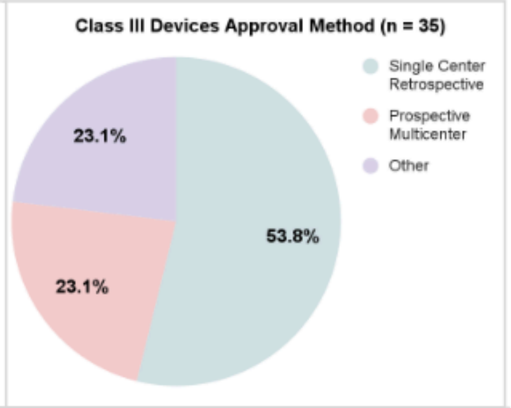
Clinical Evaluation of Operative Management Devices:

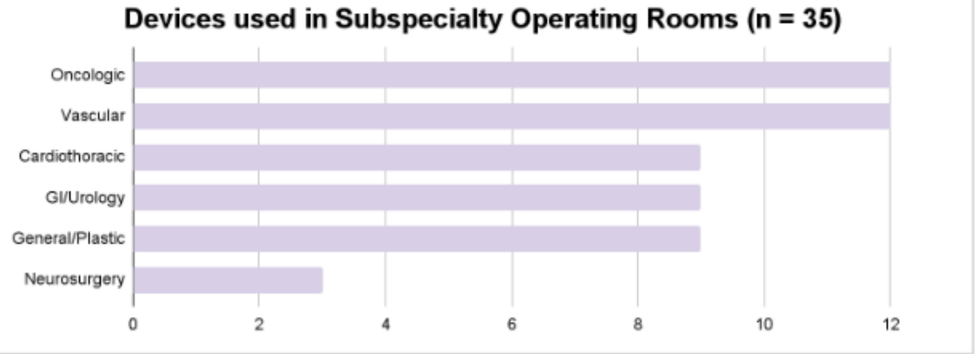
- 37% of devices classified as Class III
- 54% of Class III devices tested on single-center retrospective data
- 23% of Class III devices underwent prospective multicenter randomized trials

PMA example:

510(k) example:







Conclusions

Since this data was collected, 324 more devices were approved. Development is accelerating. Reliance on retrospective single center data is unacceptable.

Surgeons don't trust AI/ML enabled devices, and they shouldn't. Not until medical colleagues and the industry raise their standards.