AdvaMed
The MedTech Association

Artificial Intelligence in Medtech

The emergence of artificial intelligence (AI) and machine learning (ML) can be seen across multiple industries, transforming everything from healthcare to transportation. Artificial intelligence has been in the spotlight recently, but it is not a new concept to the Food and Drug Administration (FDA) or the medtech industry. AI/ML-enabled devices are subject to the same risk-based classification paradigms for standard medical devices. AI/ML devices are evaluated to performance and safety standards commensurate to the device risk AI advancements in the medtech industry are playing a major role in improving patients' lives through innovative care, reduced healthcare costs, and improved patient outcomes.

AI/ML Enabled Medical Devices ARE Regulated by FDA

25+ years of experience reviewing and authorizing AI/ML-enabled medical devices at the FDA.

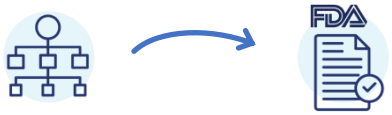
1,200+ AI/ML-enabled medical devices have been reviewed and authorized by the FDA since 1995, and the list continues to grow.* The process for reviewing AI/ML-enabled devices is the same as for all other medical devices.

The majority of all AI/ML-enabled medical devices are 510k cleared devices, meaning they are substantially similar to devices already in the market, and do not pose a high risk to patients or consumers.

Today's AI/ML products are largely utilized as tools used by clinicians and patients to augment decision making. Predominantly, these devices are not making independent decisions on diagnoses or treatment pathways; rather they provide the clinician with data and imaging results.

FDA reviews include analysis of adequate mitigation of unwanted bias and performance of the device and algorithm.

All AI/ML-enabled medical devices are cleared or approved with "locked" algorithms. This means the algorithms are not continuously learning or automatically evolving in the field. Modifications to the algorithms are subject to regulatory oversight.



Any algorithm modifications must be approved by the FDA. The FDA must authorize significant algorithm modifications. Predetermined Change Control Plans allow for more rapid device modifications to meet patients' needs while still maintaining strict FDA oversight.

The FDA's postmarket monitoring tools include adverse event reporting and recall authority. Device makers also have post-market responsibilities. The existing authorities and responsibilities provide sufficient checks and balances.

*Source: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-me

Keeping Health Care Costs Low

- AI/ML serves as a valuable tool for providers, helping to mitigate the impact of workforce shortages and improve overall efficiency in healthcare delivery.
- Imposing additional burdensome oversight and reporting requirements on AI/ML-enabled medical devices provides no added value or new protections for patients and consumers and instead could increase costs for patients.
- Companies would be forced to spend more time on duplicative reporting and less time developing new lifesaving technologies. This would stifle innovation and reduce patient access.

Examples of AI / ML-Enabled Medical Devices

CT scanners

MRI devices

PET scans

Image reconstruction tools

MRI devices

Surgical planning tools

Cardiac monitors

Bottom Line

AI/ML technology benefits patient care. AI/ML-enabled medical devices have been around for decades and have been heavily regulated by the FDA since inception. Imposing additional state regulation could risk compliance with the FDA and result in layers of onerous oversight that lack any meaningful benefit to patient safety or access.