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 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.

**600+** 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 diagnostics to assist clinicians in decision-making. Predominantly, these devices are not making independent decisions on diagnoses or treatment pathways; rather they provide the clinician with better data and imaging results.

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

Most AI/ML-enabled medical devices are cleared or approved with "locked" algorithms. The devices are not operating in the background, reacting to data and changing outputs.


Any algorithm modifications must be approved by the FDA. Predetermined Change Control Plans allow the device to adapt to meet the needs of patients while still maintaining strict oversight by the FDA.

The FDA's post-market monitoring tools like adverse event reporting and surveillance of medical devices provide additional transparency.

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

## Keeping Health Care Costs Low

- 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.
- AI/ML also serves as a valuable tool for providers, helping to mitigate the impact of workforce shortages and improve overall efficiency in healthcare delivery.

## Lifesaving AI / ML-Enabled Medical Devices

**CT scanners**

**MRI devices**

**PET scans**

**Image reconstruction tools**

**Ultrasound machines**

**Blood loss estimation tools to detect maternal hemorrhages**

**Cardiac monitors**

## Bottom Line

AI/ML-enabled medical devices have been around for decades and have been heavily regulated by the FDA since inception. Any additional regulations should prioritize patient safety and prevent onerous reporting that lacks any meaningful benefit to patient safety or access.