

Three in Four FDA Authorizations of AI Medical Devices Were in Radiology, Study Led by GigHz Founder Finds

GigHz highlights a peer-reviewed analysis of 1,430 authorization records and the broader question of what it will take to bring useful AI into more of medicine

LOS ANGELES, Oct. 6, 2026 — GigHz, a physician-founded software and research company, today announced findings from a peer-reviewed study led by its founder, Pouyan Golshani, MD. The study, published in Cureus, found that 76.5% of 1,430 artificial intelligence and machine learning-enabled medical device authorization records were reviewed by the FDA's Radiology panel. The finding raises a question for health systems investing in AI: what makes a clinical workflow ready for the technology?

The study, by Golshani and Mary S. Joseph, examined entries in the FDA's public AI-enabled device list with authorization dates from September 1995 through December 2025. Radiology accounted for 1,094 records. Together, the Radiology, Cardiovascular and Neurology panels accounted for 90.6%.

"Radiology already had digital images, common file standards and systems that move scans to the person reading them," said Golshani, an interventional radiologist and the study's lead author. "That gives developers somewhere to put AI. It doesn't tell us that radiology is easy, or that a radiologist's job is close to being automated."

The authors reported 331 authorizations in 2025. Across the full study period, Pathology accounted for nine records, Microbiology for six, and Obstetrics and Gynecology for four. These are FDA review-panel categories, which do not map directly to every specialty or setting in which a device may be used.

Growth has been rapid. Annual authorizations averaged 1.8 per year from 1995 through 2014 and 264 per year from 2023 through 2025. The field is also made up largely of developers with a single listed AI device: of 740 companies, 502 (67.8%) had a single authorized device, while 13 companies (1.8%) accounted for 247 devices (17.3%). No authorizations were recorded under a psychiatry or behavioral health review panel.

Golshani sees radiology's established digital infrastructure as one explanation for the concentration. The study describes authorization patterns; it does not test what caused them.

From available data to useful clinical decisions

“There are plenty of guideline-based decisions in internal medicine where better support could help,” Golshani said. “But the relevant information may be spread across notes, lab results, medications and prior visits. The challenge is getting the right information into the decision while the doctor can still use it.”

For developers and health systems, he argues, that means defining a specific clinical task, making the necessary data accessible and testing the tool in the workflow where it will be used. A documentation tool and a system recommending treatment require different evidence and safeguards.

“Fear of being replaced and fear of missing out can both lead to bad decisions,” Golshani said. “We need to ask what the tool actually improves, where it fails, and who is responsible when it does. I want us to keep building and test honestly. Delaying something useful has a cost, too.”

What the study measures

The analysis measures authorization records, not clinical adoption, patient benefit or physician replacement. The FDA states that its AI-enabled device list is not comprehensive. It also does not capture the full range of healthcare AI, including software functions outside device regulation. A small number of records under a review panel does not establish that the corresponding specialty lacks AI tools.

Golshani has also published a policy brief on how state oversight of clinical decision-support software relates to federal device review: <https://gighz.com/policy/clinical-decision-support-sb-503/>

Study reference

Golshani P, Joseph MS. Three Decades of Food and Drug Administration Authorizations of Artificial Intelligence/Machine Learning-Enabled Medical Devices: Persistent Specialty Concentration and the Care-Delivery Gap (1995–2025). *Cureus*. 2026;18(7):e112583. Published July 13, 2026. <https://doi.org/10.7759/cureus.112583>

About GigHz

GigHz is a physician-founded software and research company developing tools for clinical decision support, radiology reporting and practice intelligence. Golshani’s commercial work includes clinical AI software. This descriptive study does not evaluate or validate GigHz products. <https://gighz.com>

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