



GE HealthCare Tops List for Third Year in a Row with Highest Number of AI-Enabled Medical Device Authorizations

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- FDA's list of AI-enabled device authorizations includes more than 850 devices; 72 are from GE HealthCare – more than any other medical technology company

CHICAGO--(BUSINESS WIRE)--May 22, 2024-- GE HealthCare has topped a U.S. Food and Drug Administration (FDA) list of artificial intelligence (AI) enabled medical devices for the third year in a row with 72 listed 510(k) clearances or authorizations to date in the United States. GE HealthCare also topped the list when it was updated by the FDA in 2022 and 2023.

Central to the company's strategy, GE HealthCare is investing in AI and machine learning to power its vision of enabling precision care. Precision care is a holistic approach that integrates multiple technologies (e.g., advanced medical imaging, AI, and molecular diagnostics) to tailor diagnosis, treatment, and ongoing monitoring and management for optimal patient outcomes. Through this approach, the company is tackling the industry's toughest challenges including data overload, physician burnout, and real-time operational efficiency by developing purpose-built solutions powered by AI that enable practitioners to deliver high-quality, precision care.

"GE HealthCare is committed to pushing the boundaries of what is possible, utilizing advanced technologies like AI, to help deliver the future of healthcare. We are leveraging our deep industry expertise, and the unique capabilities honed through offering leading medical devices for more than 125 years to create solutions that solve our customers' biggest challenges. GE HealthCare's continued leadership in AI-based medical device authorizations shows our dedication to deliver ground-breaking technology that transforms healthcare and enhances patient outcomes," said Dr. Taha Kass-Hout, Chief Science and Technology Officer at GE HealthCare.

The FDA's webpage, [Artificial Intelligence and Machine Learning \(AI/ML\)-Enabled Medical Devices](#), provides a list of authorized devices, granted through 510(k) clearances, De Novo requests, or by premarket approval (PMA). Included in the list are 72 GE HealthCare 510(k) clearances or authorizations, including those from recently acquired companies, BK Medical, Caption Health and MIM Software. Examples include:

- **Precision DL** is our innovative deep learning-based image processing software that is engineered to provide increased small, low-contrast lesion detectability compared to our conventional Time-of-Flight PET/CT scanner¹.
- **Contour ProtégéAI+** (MIM Software) automatically generates contours for radiation oncology treatment planning, which helps reduce simulation to treatment times. Editing can be performed, if necessary, by the Dosimetrist or Physicist.
- **Caption Interpretation Automated Ejection Fraction Software** (Caption Health) is used to process previously acquired transthoracic cardiac ultrasound images, store the images, manipulate them, and make measurements on images using an ultrasound device, personal computer, or a compatible DICOMcompliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.
- **bkActiv** (BK Medical) provides high-resolution images with superb anatomical details for visualization of structures and performing confident surgical procedures and includes Prostate Volume Assist (PVA), an AI software feature to automate the manual process for generating prostate volume measurements. PVA is also available on the bk3000/5000 and bkSpectro active imaging systems.

For more information about GE Healthcare's AI-enabled medical device and enterprise digital solutions, visit [here](#).

¹ At matched scan time and injected dose. Detectability using clinical data with an inserted 8 mm diameter liver lesion of known location and 2:1 contrast using a CHO model observer, comparing SNR from Omni Legend 32 cm with QCHD and Precision DL to SNR from Discovery™ MI 25 cm with QCFX.

About GE HealthCare Technologies Inc.

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 125 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are a \$19.6 billion business with approximately 51,000 colleagues working to create a world where healthcare has no limits.

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