GE HealthCare Tops List with Highest Number of AI-Enabled Medical Device Authorizations, Developing Innovative Solutions for Precision Care

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- FDA's list of AI-enabled device authorizations includes almost 700 devices; 58 are from GE HealthCare – more than any other medical technology company.

CHICAGO--(BUSINESS WIRE)--Oct. 24, 2023-- GE HealthCare has topped a U.S. Food and Drug Administration (FDA) list of artificial intelligence (AI) enabled medical devices with 58 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.

AI is central to the company's digital strategy, which is focused on its precision care framework that includes smart devices, targeted therapies, a disease-specific focus, and digital solutions. Precision care can bring data together in the right place at the right time, solving for inefficiencies in the clinical care workflow and improving patient care quality across the care pathway. GE HealthCare is working to unlock the full potential of AI to help customers leverage data across health care systems, solve operational and diagnosis challenges and develop personalized approaches for better patient outcomes.

"We are still in the nascent stages of AI development, and its potential to redefine healthcare is immense. From bedside predictions, patient monitoring, early diagnosis, to guided screening, AI's potential for contributions to customization, precision, cost-saving, access, and health equity is unparalleled. GE HealthCare's continued leadership in AI-based medical device authorizations underscores our dedication to deliver ground-breaking technology. Our goal is to transform healthcare and enhance patient outcomes," said Dr. Taha Kass-Hout, Chief 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 58 GE HealthCare 510(k) clearances or authorizations, including those from recently acquired companies, BK Medical and Caption Health. Examples include:

- **Sonic DL** is a deep learning technology for faster magnetic resonance imaging (MRI) scans. This groundbreaking technology utilizes advanced artificial intelligence algorithms to significantly reduce scan time to a single heartbeat. By harnessing the power of deep learning, Sonic DL optimizes imaging protocols and image reconstruction, enabling healthcare providers to perform MRI scans more efficiently, slashing scan time by up to 83%[1].
- **Auto Segmentation** is a deep learning algorithm-based application that reads CT images and automatically contours and labels the organs at risk (OARs) for radiation therapy workflows to help accelerate the process.
- **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 scanner[2].
- **Caption Guidance** (Caption Health) is artificial intelligence (AI)-driven technology that provides real-time guidance to users for capturing diagnostic-quality cardiac ultrasound images. GE HealthCare acquired Caption Health in February 2023 and recently announced its Venue Family of point-of-care ultrasound systems is the first among its ultrasound products to incorporate this scan guidance technology.

For more information about GE Healthcare's AI-enabled medical device solutions, visit here.

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 100 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 an $18.3 billion business with 50,000 employees working to create a world where healthcare has no limits.

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[1] Sonic DL™ vs fully sampled cardiac CINE acquisition.

[2] 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.

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