



GE Healthcare Tops List with Highest Number of AI-Enabled Device Authorizations, More Than Any Other Medical Technology Company

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Of the more than 500 devices included by the U.S. FDA on a recently updated list of AI-enabled device authorizations, 42 are from GE Healthcare, a milestone that highlights the impact of the company's digital strategy.

Chicago - October 20, 2022 – On a recently updated FDA list of artificial intelligence (AI) enabled medical devices, GE Healthcare had the highest number of authorizations, with 42 listed 510(k) clearances to date, in the United States.

This reflects execution on the company's AI strategy, which is centered on addressing three of healthcare's largest challenges: health system efficiency and access, health outcomes, and system interoperability and workflow integration.

GE Healthcare's leading AI strategy includes Edison Health Services. Edison Health Services is GE Healthcare's software technology that is designed to aggregate data from multiple sources and vendors to enable clinical applications that support integrated care pathway management and holistic views of each patient. It is designed to be vendor agnostic and can include a healthcare specific AI toolkit for building and running applications.

"The future of healthcare is harnessing raw data and using it to help clinicians provide better patient care. For AI to be effective, it should be seamless and within existing workflows, while uncovering patterns that complement those generated by humans," said Vignesh Shetty, Senior Vice President & General Manager, Edison AI & Platform, GE Healthcare. "GE Healthcare's digital strategy is to look at AI to help clinicians achieve clinical and operational outcomes that create maximum impact for patients, providers and health systems. From big iron MRI scanners used by doctors to detect tumors on the prostate gland to mobile x-ray units in the ER or ICU that technicians use to image the lungs of COVID patients at their bedside, we are seeing a tangible impact with our AI embedded on the device where and when clinicians need it. AI is an incredible lever to tackle problems at a speed and scale that our providers are coming to expect, to help save lives and improve outcomes for millions of patients everywhere."

The FDA's webpage, [Artificial Intelligence and Machine Learning \(AI/ML\)-Enabled Medical Devices](#), provides a list of devices that have been authorized by FDA via 510(k) clearance, by granting De Novo requests, or by premarket approval (PMA). Included in the list are 42 GE Healthcare 510(k) clearances for AI-powered and data-driven solutions across the company's wide portfolio of products. These products are designed to help encourage greater diagnostic confidence across multiple care pathways such as oncology, cardiology, and neurology, by helping to ease the burden of care and improve workflows for healthcare systems worldwide. Examples include:

- [Air Recon DL](#) provides revolutionary MR imaging with its deep learning based image reconstruction algorithm. The technology is integrated on a number of products including [Signa Premier](#) and [Signa Hero](#).
- [Critical Care Suite 2.0](#) offers an industry-first collection of AI algorithms embedded on a mobile x-ray device for case prioritization, automated measurements, and quality control. Its AI algorithm helps clinicians assess Endotracheal Tube (ETT) placements and care for critically ill patients who require ventilation. [AMX Navigate](#) is portable x-ray technology featuring Critical Care Suite 2.0, a Zero Click Exam workflow solution and power-assisted Free Motion telescoping column.
- [Liver ASSIST Virtual Parenchyma](#)¹ is a 3D visualization software solution designed to provide AI-based virtual parenchymography to help clinicians simulate injections dynamically and perform liver embolization procedures with confidence.
- [Voluson 22](#) is a Women's Health ultrasound system that provides improved image quality and specialized clinical tools to help see more anatomical detail with greater certainty, and enabling the best possible patient care.
- [Revolution Ascend](#) is a 75 cm wide-bore CT system designed to make the CT process faster, more intuitive, and more approachable, while also providing the image quality clinicians expect. The product uses an AI-based workflow solution, a smart user interface, cutting-edge technology and access to Smart Subscription to help simplify, streamline and automate the CT experience.

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

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About GE Healthcare:

GE Healthcare is the \$17.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison Health Services software platform. With over 100 years of healthcare industry experience and around 48,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

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¹ Liver ASSIST Virtual Parenchyma solution includes Hepatic VCAR and FlightPlan for Liver with Parenchyma Analysis option and requires AW workstation with Volume Viewer, Volume Viewer Innova, Vision 2, VesselIQ Xpress, Autobone Xpress.