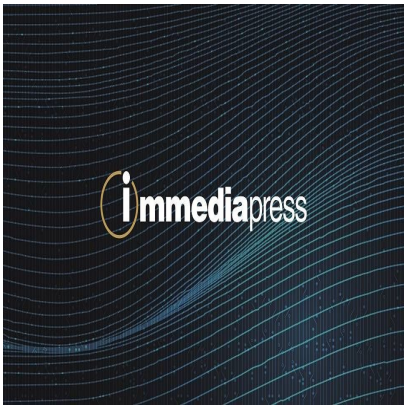

Seno Medicalâ??s Next-Generation ImagioÂ® Imaging System Obtains European Union (EU) Medical Device Regulation (MDR) CE Mark Certification

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

The CE Mark certification enables Seno Medical to market and sell the latest version of its ImagioÂ® Imaging System with opto-acoustic, sound, and artificial intelligence in the European Union.

SAN ANTONIO, Jan. 28, 2026 /PRNewswire/ â?? Seno Medical has received CE Mark certification for its next-generation ImagioÂ® Imaging System, Model 9100. EU MDR CE Mark indicates that a medical device meets the stringent safety, performance, and quality standards established globally, assessed by notified bodies approved for granting certification in the EU, and is mandatory for sale of product in the European Union and beyond.

â??EU MDR certification is one of the most challenging regulatory processes, and we are so pleased to have achieved this significant milestone for our most recent version of the ImagioÂ® System,â?• commented Tom Umbel, CEO of Seno Medical. â??ImagioÂ® delivers a revolutionary leap forward in patient care, and we are thrilled to be able to collaborate with our European colleagues to improve diagnostic processes for providers and patients.â?•

The ImagioÂ® System helps physicians, facilities, and other qualified healthcare providers differentiate between benign and malignant breast lesions using a novel combination of artificial intelligence (AI) â?? SenoGramÂ®, ultrasound, and opto-acoustic imaging technology to characterize and differentiate masses that may â?? or may not â?? require more invasive diagnostic evaluation. Seno Medical received its first CE Mark under MDD in 2014. This updated market-optimized design of the ImagioÂ® Imaging System, Model 9100, utilizes state-of-the-art OA imaging technology with native AI clinical decision support.

Senoâ??s ImagioÂ® technology combines light, sound, and AI to deliver new information never before available. Opto-acoustic imaging is a new modality in medical imaging that combines functional, anatomic, and morphologic information using light (laser optics or opto-acoustics) and sound waves plus proprietary artificial intelligence (SenoGramÂ®) to produce high-

resolution, high-contrast images with AI decision support for clinicians. The result is a diagnostic functional imaging modality that increases diagnostic confidence.

ImagioÂ® is non-invasive, has no ionizing radiation, does not use contrast agents, does not require the compression required in mammography, and does not have body habitus limitations as with MRI. ImagioÂ® provides clinicians with real-time information and the ability to provide same-day results. Incorporating ImagioÂ® into a center can improve workflow efficiency and help lower stress and anxiety in patients.

The system is indicated for use by trained and qualified healthcare providers to evaluate palpable and non-palpable breast abnormalities in adult patients who are referred for diagnostic imaging breast work-up following clinical presentation or other imaging examinations such as screening mammography.

Seno Medical Instruments, Inc. is a San Antonio, Texas-based medical imaging company committed to improving the efficiency â?? and reducing the complexity â?? of cancer diagnostics through its new modality: opto-acoustic imaging. Approved by the U.S. FDA in January 2021, with supplemental approval in June 2022, Senoâ??s ImagioÂ® Imaging System is a new modality combining light, sound, and integrated A.I. to provide information not previously available to clinicians. The result is substantially improved confidence in diagnostic results that leads to real-time assessments and streamlined care pathways. To learn more about Seno Medicalâ??s ImagioÂ® imaging technology and applications, visit www.SenoMedical.com.

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Categoria

1. Comunicati

Tag

1. ImmediaPress

Data di creazione
Gennaio 28, 2026
Autore
redazione