Seno Medical Instruments Appoints Ann Waterhouse as VP, Quality Assurance and Regulatory Affairs

SAN ANTONIO, April 24, 2017 /PRNewswire/ -- Seno Medical Instruments, Inc. (Seno Medical), the leader in improving the process of diagnosing breast cancer through the development of an opto-acoustic (OA/US) imaging device, today announced the appointment of Ann Waterhouse as Vice President of Quality Assurance and Regulatory Affairs. Ms. Waterhouse previously served as the Director of Regulatory Affairs at Hill-Rom in Batesville, IN. Ms. Waterhouse brings 18 years of regulatory and quality experience across a broad range of medical devices. She has been involved in Fortune 500 international expansion, start-up companies and developing and growing quality and regulatory functions.

"Ann has made an immediate impact in our organization and is joining Seno Medical at a critical stage in our FDA approval and commercialization process. We are pleased to have this type of talent join our leadership team," said Tom Umbel, CEO of Seno Medical. "Ann's regulatory knowledge and reputation within the FDA will be an important asset as we embark on our final phase in this process for the Imagio™ OA/US breast imaging system."

Ms. Waterhouse has been part of successful leadership teams who worked on closure of FDA warning letters, 510(k) and PMAs, international registrations and expanding global footprint, as well as mergers and acquisitions. Most recently at Hill-Rom, she was integral to working through many regulatory matters and implemented a Regulatory Intelligence program focused on the directional and dedicated design of innovative products. Ms. Waterhouse has been dedicated to the education and retention of employees at both a company level and as part of the Indiana Medical Device Manufacturers Council (IMDMC).

"I am excited to join Seno Medical. There is an energy at this company to do innovative work that is not often felt in larger organizations. The passion and teamwork are also more evident, and this technology will have an effect on patient quality of life that is immeasurable," said Ms. Waterhouse.

The Imagio™ OA/US breast imaging system was designed to identify the two functional hallmarks of cancer: the presence of abnormal blood vessels (tumor angiogenesis) and the relative reduction in oxygen content of blood that occurs in cancer compared to benign masses and normal tissues. The technology used by Seno Medical's OA/US is non-invasive and does not require patient exposure to contrast agents, ionizing radiation (x-ray) or radioisotopes, which are required for other modalities that are capable of functional imaging, including magnetic resonance imaging (MRI) or positron emission tomography (PET). The Imagio breast imaging system is currently an investigational device in the United States.

The technology currently has CE mark outside the U.S. and is targeting Premarket Approval submission to the FDA in 2017.

About Seno Medical Instruments, Inc.
Seno Medical Instruments, Inc. is a San Antonio, Texas-based medical imaging company committed to the development and commercialization of a new modality in cancer diagnosis: opto-acoustic imaging. Seno Medical's Imagio breast imaging system fuses opto-acoustic technology with ultrasound (OA/US) to generate functional and anatomical images of the breast. The opto-acoustic images provide a unique blood map around suspicious breast masses while the ultrasound provides a traditional anatomic image. Through the appearance or absence of the two hallmark indicators of cancer – angiogenesis and deoxygenation – Seno Medical believes that the Imagio™ OA/US breast imaging system will be a more effective tool to help radiologists confirm or rule out malignancy than current diagnostic imaging modalities – without exposing patients to potentially harmful ionizing radiation (x-rays) or contrast agents. To learn more about Seno Medical's OA/US imaging technology and applications, visit www.SenoMedical.com.

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