Seno Medical Instruments receives CE Mark for Imagio® breast imaging system

SAN ANTONIO, TEXAS – April 10, 2014 – Seno Medical Instruments, Inc., the company pioneering the development of opto-acoustic technology as a new tool to improve the process of diagnosing breast cancer, announced today that it has received the CE Mark for Imagio®, a new opto-acoustic imaging system, in Europe. Seno is in the middle of its Pivotal Study whose purpose is to determine if this technology will provide new information to the physician to decide if a woman may avoid negative (unnecessary) biopsies.

“I am very pleased that we have achieved this important milestone for Seno,” said Seno CEO, Janet Campbell. “Experts recently presented data from the Imagio feasibility study at the European Congress of Radiology in Vienna, and it was enthusiastically received by European key opinion leaders. The CE Mark means we can now commercialize this important new breast imaging system in Europe and gives us the opportunity to continue developing our relationships with physicians and regulators in the EU.”

Seno’s Imagio fuses opto-acoustics, a technology based on “light-in and sound-out,” with traditional ultrasound. The opto-acoustic images provide a unique blood map in and around suspicious breast masses. Cancerous tumors grow relatively quickly and require significant amounts of blood and oxygen, so a network of blood vessels grows around cancerous masses. Imagio provides images of these networks and a map of relative oxygen-rich or oxygen-deprived blood. Radiologists believe that Imagio images depicting significant vascular structures and low oxygen levels are likely to indicate cancers. Unlike other functional fusion technologies, Imagio uses no x-rays (ionizing radiation) or injectable contrast agents to obtain its information, thereby reducing the patient’s exposure to any potentially harmful aspects of imaging.

In 2012, The European Journal of Cancer estimated that 464,000 new cases of breast cancer were diagnosed in Europe. Each year millions of women around the world undergo core needle or surgical breast biopsies after a suspicious mass is found through breast imaging or self-exams. Studies show that more than 80% of these biopsies reveal benign pathology after they are analyzed in a laboratory.

The Imagio Pivotal Study is ongoing in the U.S. and includes 16 leading hospitals and imaging centers throughout the country. The study will form the basis of the company’s pre-market approval application (PMA) to seek U.S. approval from the U.S. Food and Drug Administration (FDA).