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Perimeter Medical Imaging Receives FDA Clearance for OTIS™ Optical Tissue Imaging System

*** Perimeter equips clinicians with ground-breaking intra-operative imaging tool***

TORONTO--(BUSINESS WIRE)-- Perimeter Medical Imaging, Inc., an innovative medical imaging company whose mission is to revolutionize tissue removal surgery for surgeons and patients, today announced receipt of U.S. Food and Drug Administration (FDA) 510(k) clearance for its OTIS™ 1.0 Optical Coherence Tomography System.

The OTIS™ provides high-resolution, real-time imaging of the periphery of excised tissue, enabling clinicians to visualize sub-surface structures up to 2 mm below the surface. These sub-surface structures would otherwise not be evident until days – and often weeks – later when conventional histology slides are available for review.

Dr. Ted James, Medical Director of Skin & Soft Tissue Surgical Oncology at the University of Vermont College of Medicine, and advisor to Perimeter, expressed excitement over potential applications of this novel imaging tool. “As a surgeon specializing in breast cancer, melanoma and extremity sarcoma, I am aware of the limitations in current intra-operative tissue assessment techniques, which rely primarily on palpation and visual inspection. In certain cases, more than 1 in 4 patients are called back for a second surgery once conventional histology has been reviewed. That’s an upsetting statistic, and highlights the need for a better tool. The information provided by OTIS™ could better equip surgeons to improve patient care during a wide variety of tissue removal surgeries.”

The OTIS™ system is a platform technology for use on all excised tissue types. Working with clinical partners, Perimeter has established a world-class reference atlas of tissues including thyroid, skin, breast, cervical, prostate and ovarian, demonstrating compelling correlation between OTIS™ images and histology (considered the clinical gold standard). Perimeter plans to continue expansion of the atlas now that FDA clearance has been granted. Perimeter’s collaborators, including key opinion leaders from leading surgical centers in Canada and the United States, are planning use of the device in a major clinical adoption study slated to begin at the end of 2016.

“Perimeter’s mission is to deliver effective, intuitive surgical tools to improve patient care. By providing subsurface information in real time, clinicians will have greater confidence in their assessments, leading to better accuracy in intervention,” said Paul Weber, Perimeter’s President and CEO. “The OTIS™ 510(k) clearance is a significant milestone for Perimeter. I’d like to recognize the contributions of our clinical partners, investors, regulators and employees, who are all aligned in their mission to build and bring to market tools to address recognized clinical needs and by doing so, improve patient care.”

About the OTIS™ 1.0 Optical Tissue Imaging System

The OTIS™ is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization. The OTIS™ is the first FDA-cleared device to provide automated, rapid collection of Optical Coherence Tomography (OCT) images. Previously-cleared devices required the clinician-user to move his/her hand to collect “point-by-point” images, increasing operator workload and generating images from only a small number of points on the specimen. The OTIS™ leverages Perimeter’s proprietary Wide-Field Optical Coherence Tomography Imaging technique to overcome this limitation, leading to rapid, intuitive imaging of the entire specimen.

About Perimeter Medical Imaging Inc.

Perimeter Medical develops, patents, and commercializes advanced surgical imaging tools that allow surgeons, radiologists and pathologists to better assess microscopic tissue structures during the surgical procedure. Perimeter’s OTIS™ is the only solution that provides clinicians with automated, high-resolution visualization of the entire surface of the removed tissue specimen, enabling better in-surgery decisions. Perimeter is a privately owned Canadian company. For more information, visit www.perimetermed.com.

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