

News from



IMALUX CORPORATION RECEIVES FDA CLEARANCE FOR OCT IMAGING DEVICE

Imalux OCT Imaging System
For Release: Immediate

Cleveland, Ohio, March 5, 2004 -- Imalux Corporation ("Imalux"), a developer and marketer of medical imaging systems based on Optical Coherence Tomography ("OCT") technology, announced today that the U.S. Food & Drug Administration (FDA) has cleared the Imalux OCT Imaging System for market release. The FDA decision will allow the company to proceed with manufacture and marketing of the device.

"This is an important milestone for both Imalux and the Healthcare community," noted J. Lloyd Breedlove, President and Chief Executive Officer. "The 510(k) clearance allows us to provide the sixth imaging modality, Optical Coherence Tomography, for a broad range of medical imaging applications. The Imalux Imaging System fills a gap in current imaging modalities and has the potential to create a large new segment of the medical imaging industry."

The Imalux OCT Imaging System provides real-time, high spatial resolution, two-dimensional, cross-sectional depth visualization of tissue microstructure. The compact, point-of-care system creates images utilizing harmless near infrared light. The spatial resolution of the System is on the order of 0.01 mm, surpassing conventional ultrasound imaging by an order of magnitude.

Mr. Breedlove further stated, "The Imalux OCT Imaging System provides an opportunity for a single episode of care. In one session, at the point-of-care, the clinician now has a tool for evaluation of structural disruptions of tissue, which can assist in diagnosis and in some cases permit immediate treatment based on that evaluation. We believe that enhanced clinical information, patient peace of mind and overall cost savings by the reduction of multiple procedures are just a few of the benefits our System will provide the Healthcare community."

The Imalux OCT technology was originally developed in Russia at the Institute of Applied Physics and, over the past five years, has been under evaluation with physicians in a number of specialty areas at The Cleveland Clinic Foundation, The George Washington University Medical Center, as well as other leading medical institutions.

About Imalux

Imalux is a Cleveland-based corporation that is commercializing Optical Coherence Tomography ("OCT") technology originally developed at the Institute of Applied Physics of the Russian Academy of Sciences. The technology came to Cleveland with the help of local investors and service providers, and was refined and evaluated with over 2,000 patients worldwide, including over 300 at The Cleveland Clinic Foundation.

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