NinePoint Medical Receives Additional FDA 510(k) Clearance for NvisionVLE Imaging System

The Associated Press

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr 26, 2013--NinePoint Medical, Inc., an emerging leader in the development of medical devices for in vivo imaging, today announced that it has received an additional 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its NvisionVLE ™ Imaging System, expanding the system's indication to include imaging of esophageal tissue microstructure. In January 2012, the company announced 510(k) clearance from the FDA to market its NvisionVLE Imaging System for use as an imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross sectional, real-time depth visualization.

"The NvisionVLE Imaging System is the first and only volumetric, optical coherence tomography device cleared by the FDA for endoscopic imaging, and now imaging of esophageal tissue microstructure," said Charles Carignan, M.D., president and chief executive officer of NinePoint Medical. "Expanded FDA 510(k) clearance for imaging of the esophagus represents an important milestone as we progress toward commercializing the NvisionVLE Imaging System this year. We believe that the NvisionVLE Imaging System will allow physicians to see more esophageal tissue for biopsy and treatment procedures, providing them with valuable imaging information."

About NinePoint Medical, Inc.
NinePoint Medical, Inc. is a transformational medical device company developing innovative, real-time, in vivo imaging devices focused on dramatically improving patient care. The proprietary NvisionVLE™ Imaging System will enable physicians and pathologists, for the first time, to view real-time, high-resolution, volumetric images of organs and tissues up to 3mm deep at better than 10 micron resolution. NinePoint is preparing for a commercial launch of the NvisionVLE Imaging System in the U.S. in May 2013. The NvisionVLE Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization. The safety and effectiveness of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated. Headquartered in Cambridge, Mass., NinePoint is backed by Third Rock Ventures and Prospect Venture Partners. For more information, please visit www.ninepointmedical.com.

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