

For Immediate Release

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NinePoint Medical Announces FDA Clearance of an Artificial Intelligence Software Upgrade for the NvisionVLE® Imaging System

Bedford, Mass. – November 5, 2018 – [NinePoint Medical, Inc.](#), a transformative medical device company pioneering the use of a real-time imaging platform for gastrointestinal applications, announced today that it has received U.S. Food and Drug Administration (FDA) clearance to market its Intelligent Real-time Image Segmentation™ (IRIS) software upgrade for its flagship product, the NvisionVLE Imaging System. IRIS, an artificial intelligence-based platform for image feature segmentation, is the first tool of its kind approved for use in imaging of esophageal tissue.

The NvisionVLE Imaging System allows physicians to perform a Volumetric Laser Endomicroscopy (VLE) procedure that produces real-time, high-resolution cross-sectional images. This system enables gastroenterologists to thoroughly evaluate the esophageal tissue surface and sub-surface for potential disease that may not be visible with conventional medical imaging technologies such as endoscopy and ultrasound. The new IRIS upgrade utilizes state of the art machine learning algorithms to segment and visualize esophageal image features in real-time, to assist clinicians as they identify and target regions of interest during an endoscopic procedure.

The clearance of IRIS marks the first product addition to the NvisionVLE Imaging System family since NinePoint Medical [began a strategic collaboration](#) with its worldwide distributor, Merit Medical Systems, Inc. (NASDAQ: [MMSI](#)). “We are thrilled to continue to see the innovation and development of high quality products from our collaborators at NinePoint,” said Fred P. Lampropoulos, Chairman and CEO of Merit Medical. “The NvisionVLE Imaging System has been a great strategic addition to the Merit Medical family of GI products, and we look forward to continuing to work together on future product releases.”

“The clearance of the IRIS product marks the successful culmination of a multi-year development effort within our organization, and with the Food and Drug Administration,” commented Eman Namati, Ph.D., President and CEO of NinePoint Medical. “This product is something we at NinePoint, and our customers, are very excited to bring to market. We pride ourselves in customer responsiveness and innovation, key inputs to this new product. We are eager to roll this out in a controlled-market release in the coming months prior to making the technology more broadly available.”

About the NvisionVLE Imaging System

The NvisionVLE Imaging System provides a unique and clinically valuable new perspective on esophageal disease - the ability to image within the wall of the esophagus. By providing a high-resolution, real-time scan of the esophagus using Optical Coherence Tomography (OCT) – a technology similar to ultrasound but using infrared light rather than sound waves - the system enables physicians to view structures not evident with conventional imaging, and potentially identify disease that would have otherwise been missed. With the Real-time Targeting™ feature, physicians can not only locate, but mark areas of interest. This marking feature, in combination with an improved workflow, enables more accurate targeting, potentially leading to improved diagnosis and more effective therapeutic decisions for patients.

The NvisionVLE Imaging System has been cleared by the FDA and is commercially available in the U.S. It 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 and may be used to mark areas of tissue. The software provides segmentation and display of common imaging features, including hyper-reflective surface, layering, and hypo-reflective structures. The safety and efficacy of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.

About NinePoint Medical, Inc.

NinePoint Medical is a privately-held medical device company that designs, manufactures, and sells an Optical Coherence Tomography (OCT) imaging platform for clinical use in gastroenterology, pulmonology, urology, gynecology, and ENT, for the evaluation of human tissue microstructure. Using proprietary imaging and software technology, the Company is committed to enabling quicker diagnosis of disease and more effective treatments, while reducing the overall cost of healthcare. NinePoint Medical is located in suburban Boston, Massachusetts. For more information, please visit www.ninepointmedical.com.

About Merit

Founded in 1987, Merit Medical Systems, Inc. is engaged in the development, manufacture and distribution of proprietary disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy. Merit serves client hospitals worldwide with a domestic and international sales force and clinical support team totaling in excess of 300 individuals. Merit employs approximately 5,600 people worldwide with facilities in South Jordan, Utah; Pearland, Texas; Richmond, Virginia; Malvern, Pennsylvania; Rockland, Massachusetts; San Jose, California; Maastricht and Venlo, The Netherlands; Paris, France; Galway, Ireland; Beijing, China; Tijuana, Mexico; Joinville, Brazil; Markham, Ontario, Canada; Melbourne, Australia; Tokyo, Japan; and Singapore.