November 2, 2018

NinePoint Medical, Inc.
Eman Namati
President and Chief Executive
Officer 12 Oak Park Drive
Bedford, Massachusetts 01730

Re: K182616
Trade/Device Name: NvisionVLE Imaging System, NvisionVLE Optical Probe, NvisionVLE Inflation System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: September 21, 2018
Received: September 21, 2018

Dear Eman Namati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warning device's labeling:

1. The Nvision VLE® Imaging System is intended to provide an image of tissue microstructure. 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.

Furthermore, the indication for use "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 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." must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and

Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William H. Maisel -S

William H. Maisel, MD, MPH
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)* K182616

Device Name

NvisionVLE Imaging System

Indications for Use *(Describe)*

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 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 NvisionVLE® Imaging System is intended to provide an image of tissue microstructure. 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.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

NinePoint Medical, Inc.'s NvisionVLE® Imaging System

Submitter

NinePoint Medical, Inc.
12 Oak Park Drive
Bedford, MA 01730

Official Contact:

Eman Namati, Ph.D.
President and Chief Executive Officer, NinePoint Medical, Inc.
(617) 250-7147 (direct)

Date Prepared: September 21, 2018

Name of Device: NvisionVLE® Imaging System
Common or Usual Name: Optical Coherence Tomography Imaging System
Classification Name: Ultrasonic pulsed echo imaging system
Regulatory Classification: 21 C.F.R. § 892.1560
Product Code: NQQ
Regulatory Class: Class II

Predicate Device: NvisionVLE Imaging System (K153479)

Intended Use / Indications for Use

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 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 NvisionVLE® Imaging System is intended to provide an image of tissue microstructure. 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.

Device Description

The NinePoint Medical NvisionVLE® Imaging System is a high-resolution volumetric imaging system based on optical coherence tomography (OCT). In an analogous fashion to ultrasound imagery, OCT images are formed from the time delay and magnitude of the signal reflected from the tissue of interest. The NvisionVLE Imaging System employs an advanced form of OCT known as swept-source OCT (SS-OCT), or Optical Frequency Domain Imaging (OFDI), in combination with a scanning optical probe to acquire high-resolution, cross-sectional, real-time imagery of tissue called Volumetric Laser Endomicroscopy (VLE).

In addition to the imaging capability, the device provides a means of marking areas of tissue with an additionally integrated 1470nm laser. The ability to create temporary laser marks directly on tissue enables a clinician to place visual reference marks on tissue regions of clinical interest immediately following their identification via VLE. The device consists of the following five main components and accessories: (i) a mobile NvisionVLE Console with an integrated computer and two touch-screen interfaces; (ii) proprietary NvisionVLE Software used to acquire, process, and visualize VLE images; (iii) a single-use, sterile NvisionVLE Marking Probe that is inserted through the working channel of an endoscope; (iv) a single-use, sterile NvisionVLE Inflation System that is used to inflate the Marking Probe's balloon to facilitate placement; and (v) a Probe Lock Accessory to prevent longitudinal motion of the Marking Probe within the endoscope.

The purpose of this 510(k) submission is to add an artificial intelligence software tool referred to as Image and Visualization Enhancements (IVE) to the previously cleared, predicate NvisionVLE Imaging System (K153479). The IVE software module allows enhanced visualization (segmentation and colorized display) of the following commonly observed image features (also referred to as IVE features): (1) hyper-reflective surface, (2) layering and (3) hypo-reflective structures. The segmentation algorithm was developed using an artificial intelligence machine learning technique known as deep learning. Here, an artificial neural network was trained with manually labelled examples of each feature and then locked for real-time inference on new image data acquired by the device. Display of each feature can be toggled via the user interface, where a respective color overlay is presented. The default display of the IVE features is disabled and the standard VLE image data displayed per the cleared NvisionVLE Imaging System. Segmentation of these structures are based on existing image features, and IVE simply increases the conspicuity via the color overlays, thus aiding image review. It is a convenience tool and a resource for the clinician and as such, it does not alter the standard of care or the role of the physician in reviewing and assessing images generated by the system.

Performance Data

A series of bench tests were conducted to assess the performance and safety of the device. All acceptance criteria were met, supporting substantial equivalence for the subject device. A brief summary of the performance testing is described below.

Testing was conducted to confirm that the software was able to segment IVE features with pre-established performance metrics, based on a comparison of the IVE segmentation output against a ground truth data set.

Specifically, the objective of the testing was to evaluate the ability of the software to detect each IVE feature including tissue surface, regions with layering and absence of layering and hypo-reflective structures. The target true positive and true negative detection fractions were prospectively set.

Data used for testing was obtained from a sequestered subset (~40%) of the 1000-patient 18-site NvisionVLE Clinical Registry study. Here, patients were randomly chosen and regions of interest (ROI), defined as 30° segments of a 360° transverse image, were selected for testing.

Assessment was performed by comparing ground truth data generated by human observers, with the software-based detection of the IVE features. Ground truth consisted of ROIs labeled by trained experts in clinical interpretation of VLE imagery.

The final performance testing evaluated the following:

- 192 positive ROIs and 266 negative ROIs of Hypo-Reflective Structures
- 229 positive ROIs and 225 negative ROIs of regions with/without layering
- 253 positive ROI and 220 negative ROIs of tissue surface.

The results of the observed true positive and true negative detection fractions with Lower Limit of 95% Exact Two-Sided Confidence Interval (Clopper Pearson) of the performance evaluation of the Image and Visualization Enhancement are presented in **Table 1**.

Table 1: Observed True positive and true negative detection fractions with Lower Limit of Two-Sided Exact 95% Exact Confidence Intervals

ROI	True Positive Detection Fraction (%)	Lower Limit of Exact 95% Confidence Intervals	True Negative Detection Fraction (%)	Lower Limit of Exact 95% Confidence Intervals
Tissue Surface	92.9 (235/253)	89.0	95.0 (209/220)	91.2
Layering	89.6 (205/229)	84.8	97.8 (220/225)	94.9
Hypo-Reflective Structures	91.1 (175/192)	86.2	92.9 (247/266)	89.1

As a result of this study, the tissue surface detection showed a true positive detection fraction of 92.9 % (Lower Limit of Exact 95% Two-Sided Confidence Interval 89.0%) and true negative detection fraction of 95.0% (Lower Limit of Exact 95% Two-Sided Confidence Interval 91.2%). The regions with/without layering showed a true positive detection fraction of 89.5% (Lower Limit of Exact 95% Two-Sided Confidence Interval 84.8%) and true negative detection fraction of 97. 8% (Lower Limit of Exact 95% Two-Sided Confidence Interval 94. 9%). The Hypo-Reflective Structures showed a true positive detection fraction of 91.1% (Lower Limit of Exact 95% Two-Sided Confidence Interval 86.2%) and true negative detection fraction of 92.9% (Lower Limit of Exact 95% Two-Sided Confidence Interval 89.1%). Based on the target performance specifications, true positive and negative detection fractions for all three segmented features exceeded their target value with a significance level $\alpha < 0.05$.

Substantial Equivalence

The subject and predicate NvisionVLE Imaging Systems have the same intended use and similar indications, technological characteristics and principles of operation. The changes in the proposed device do not alter the tissue microstructure in the VLE image, but provide enhanced visualization of commonly observed features and thus none of the fundamental technological characteristics of the system are altered. These changes do not present different questions of safety or effectiveness than the predicate device, as confirmed by bench testing. Thus, the NvisionVLE Imaging System is substantially equivalent to the predicate device.