October 16, 2018

NinePoint Medical, Inc.
Eman Namati
President & CEO
12 Oak Park Drive
Bedford, Massachusetts 01730

Re: K182261
Trade/Device Name: NvisionVLE Imaging System, NvisionVLE Optical Probe
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: August 20, 2018
Received: August 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 section of the device's labeling:

1. The Nvision VLE Imaging System is intended to provide an image of the 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, realtime depth visualization" 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,

FDA William H. Maisel -S

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

Enclosure

Section 6
Statement of Indications for Use

510(k) Number (if known): This application K182261

Device Name: ***NvisionVLE Imaging System***

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.

Prescription Use ___ X ___ AND/OR Over-the –Counter Use _____

(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 7
510(k) Summary

1. Basic Information-Submitter:

510(k) Owner: NinePoint Medical Inc.

Address: 12 Oak Park Drive
Bedford, MA 01730
(617) 250-7190 (main number)
(617) 250-7199 (fax)

Official Contact: Eman Namati, PhD
President and CEO
NinePoint Medical, Inc.
(617) 250-7190 (main number)
(617) 250-7199 (fax)
enamati@ninepointmedical.com

Date Summary Prepared: 20 August 2018

2. Device Name:

Trade Name: *NvisionVLE® Imaging System*
Common Name: Optical Coherence Tomography Imaging System
Classification Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1560
Product Code: NQQ
Classification: Class II

3. Predicate Devices:

NvisionVLE® Imaging System, K143678

4. 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).

The device consists of the following 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 Optical 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 balloon as required, to facilitate placement; and (v) a Probe Lock Accessory to prevent longitudinal motion of the Probe within the endoscope.

5. Indications for Use Statement:

   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.

   Labeling limitation: The Nvision VLE Imaging System is intended to provide an image of the 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.

6. Technological Characteristics:

   The subject of this Special 510(k) submission is a device enhancement to provide balloon-less Low-profile Optical Probes in multiple configurations which include 20mm, 14mm and Short Working Distance (SWD) focal length optics. There are no new materials introduced with this change.

   The *NvisionVLE™ Optical Probe* is made up of an optical probe subassembly and a guide sheath. The optical probe subassembly is a fiber optic probe assembly secured inside a flexible, stainless steel torque shaft. The distal optics are housed in a stainless steel hypotube which is attached to the torque shaft. The proximal end of the optical fiber and torque shaft terminate in a standard fiber optic connector and catheter connector which interfaces with the system console. The optical probe subassembly transmits and focuses the optical light and detects the reflected light for image reconstruction.

   The guide sheath is a coaxially-designed balloon sheath. The sheath is composed of a PET balloon and a nylon shaft, or is provided without the balloon for the Low-profile Optical Probe models. The inner lumen of the

sheath is sealed, enclosing the optical probe subassembly. The guide sheath is positioned within the organ structure of interest and allows the probe to rotate in a helical pattern while positioned in the inner lumen allowing for image reconstruction of the targeted tissue.

The technological characteristics of this device are unchanged from the predicate device cleared under K143678. The balloon-less version of the probe does not affect the intended use or alter the fundamental scientific technology of the device.

7. Non-Clinical Performance data:

Functional testing of the Low-profile Optical Probes included:

- Confirmation of the proper image on the Console
- Acceptable probe lateral resolution, back reflection, and transmission rate
- Mechanical integrity of the probe/sheath tip demonstrated through tensile testing
- Functional testing to ensure the probe loads and withdraws properly

The NvisionVLE Imaging System has also been tested against and complies with the following voluntary standards:

Consensus Standard	Description
ANSI/AAMI/ISO 10993-7	Biological evaluation of medical devices: Part 7: Ethylene oxide sterilization residuals
ANSI/AAMI/ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing
ANSI/AAMI/ISO 11135:2014	Sterilization of Health Care Products – Ethylene Oxide- Requirements for Development, Validation and Routine Control of Ethylene Oxide Sterilization Process for Medical Devices
IEC 60601-1	Medical Electrical Equipment, Part 1
IEC 60601-1-2	Medical Electrical Equipment, Part 1-2, General Requirement for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility -Requirements and Tests
ISO 62304	Software Development Life Cycle

IEC 60601-2-18	Medical Electrical Equipment – Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment
IEC 60601-2-22	Medical Electrical Equipment – Part 2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60825-1	Safety of Laser Products – Part 1: Equipment Classification and requirements
IEC 60601-1-6	Medical electrical equipment Part 1-6 General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 62366-1	Medical devices -- Part 1: Application of usability engineering to medical devices

8. Substantial Equivalence:

   The NvisionVLE Imaging System has the same intended use and same indication, principles of operation, and technological characteristics as the predicate device. The minor differences with the Low-profile Optical Probe do not raise any new or different questions of safety or effectiveness.

   Nonclinical performance testing demonstrates that the NvisionVLE Imaging System is as safe and effective as the predicate device and is therefore considered substantially equivalent.