



Food and Drug Administration
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February 16, 2016

Ninepoint Medical Inc.
Dr. Eman Namati
Vice President, Research and Development
12 Oak Park Drive
Bedford, Massachusetts, 01730

Re: K153479

Trade/Device Name: Nvision VLE Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: December 2, 2015
Received: December 2, 2015

Dear Dr. 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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 Warnings 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, and may be used to mark areas of tissue” 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

William H. Maisel -S

William H. Maisel, MD, MPH
Director, Office of Device Evaluation (Acting)
Deputy Center Director for Science
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153479

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, realtime depth visualization, and may be used to mark areas of tissue.

The NvisionVLE 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.

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

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

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
Vice President, Research and Development
NinePoint Medical, Inc.
(617) 250-7190 (main number)
(617) 250-7199 (fax)
enamati@ninepointmedical.com

Date Summary Prepared: December 2, 2015

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
QUANTA System Diode Laser – K100558
Spot Endoscopic Marker – K993951

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).

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 first four components provide the previously-cleared (K143678) VLE imaging functionality of the NvisionVLE Imaging System. The device consists of a Laser Marking Unit and a Hand Controller as part of the NvisionVLE Console, and updated NvisionVLE Software for the laser marking functionality. A Probe Lock Accessory is also provided to the user as a convenience to help stabilize the Marking Probe during laser marking.

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, and may be used to mark areas of tissue.

The NvisionVLE 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. Performance Data:

A series of bench and animal tests have been conducted to assess the performance and safety of the device. Acute and short-term chronic animal studies confirmed feasibility of the laser marking method and the device in a simulated clinical environment. Laser doses of power and time were evaluated to find the optimum parameter setting to achieve marks that were both visible under VLE and White Light Endoscopy, but also deemed safe and did not result in injury. In addition, a series of bench testing was performed to establish the accuracy of marking areas of interest.

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: Ethylene oxide sterilization residuals
ANSI/AAMI/ISO 10993-1	Biological evaluation of medical devices – Part 1:Evaluation and testing
ANSI/AAMI/ISO 11135-1	Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
IEC 60601-1	Medical Electrical Equipment, Part 1
IEC 60601-1-2	Medical Electrical Equipment, Part 1-2, Electromagnetic Compatibility
ISO 62304	Software Development Life Cycle
IEC 60601-2-18	Particular requirements for basic safety and essential performance of endoscopic equipment
IEC 60601-2-22	Laser Safety
IEC 60825-1	Laser Safety

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

Clinical testing evaluated the safety and efficacy of this technology, confirming the use of the laser marking functionality for aiding a physician to further evaluate tissue regions of interest as identified on the VLE image.

7. Substantial Equivalence:

The NvisionVLE Imaging System has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate and reference devices. The minor differences in the NvisionVLE Imaging System technological characteristics do not raise any new or different questions of safety or effectiveness. Specifically, the primary predicate device and the proposed device have nearly the same technological characteristics. The main technological difference between the proposed device and the primary predicate imaging system is the addition of a marking laser, the Laser Marking Unit (LMU) subsystem, which is used to mark the tissue and is controlled via a Hand Controller. All appropriate laser safety controls have been incorporated per IEC 60825-1. The second predicate, the QUANTA laser, is the same type of laser as that added to the subject device in the Laser Marking Unit (LMU) subsystem and has the same classification and wavelength; Notably, the marking laser in the subject device has a power output that is far less (milliWatts versus Watts) than the power employed by the predicate to cut, ablate, or vaporize soft tissue. The marking laser employs only enough power to denature the soft tissue to cause a very slight degree of thermal injury.

The laser marking feature of the proposed device does not affect the intended use or risks of using the imaging tool, nor does the imaging tool affect the performance or risk profile of the marking laser. The laser marking feature is a convenience component that is added to the predicate imaging tool to create the new device, with the intended use of the new device still being that of the imaging tool, as discussed above.

Performance data demonstrates that the NvisionVLE Imaging System is as safe and effective as the predicate and reference devices. Thus, the NvisionVLE Imaging System is substantially equivalent.