July 19, 2019

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

Re: K191117
Trade/Device Name: NvisionVLE Low-profile Optical Probe
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: April 25, 2019
Received: April 26, 2019

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 OHT4: Office of Surgical and Infection Control Devices 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 device's labeling:

1. 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.

Furthermore, the indication for use "The Low-Profile Optical Probe, as part of the NvisionVLE Imaging System, is indicated for use as an imaging tool in the valuation of human tissue microstructure, including esophageal and pancreatico-biliary system tissue microstructures, by providing two-dimensional, cross-sectional, real-time 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K191117

Device Name
NvisionVLE Imaging System

Indications for Use *(Describe)*

The Low-Profile Optical Probe, as part of the NvisionVLE Imaging System, is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal and pancreatico-biliary system tissue microstructures, by providing two-dimensional, cross-sectional, real-time depth visualization.

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)*

☒ 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Traditional 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, Ph.D. President and CEO (617) 250-7190 (main number) (617) 250-7199 (fax) enamati@ninepointmedical.com
Date Summary Prepared:	25 April 2019

2. Device Name:

Trade Name: *NvisionVLE® Imaging System*
Model Number: NvisionVLE Optical Probes 95501-LP
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, K182261

4. Device Description:

The NinePoint Medical NvisionVLE® Imaging System subject to this 510(k) is a general imaging system comprised of the NvisionVLE® Console and NvisionVLE® Optical Probe.

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 or organ 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; and (iv) a Probe Lock Accessory to prevent longitudinal motion of the Probe within the endoscope.

5. Indications for Use Statement:

The Low-Profile Optical Probe, as part of the NvisionVLE Imaging System, is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal and pancreatico-biliary system tissue microstructures, by providing two-dimensional, cross-sectional, real-time depth visualization.

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.

6. Technological Characteristics:

The NinePoint Medical NvisionVLE® Imaging System cleared under K182261 consists of the NvisionVLE Console and the single-use, sterile NvisionVLE® Catheter (marketed as the NvisionVLE® Optical Probe).

The subject of this 510(k) submission is to add additional specific anatomical locations of the pancreatico-biliary tract when using the balloon-less Low-profile Optical Probe. There are no new materials introduced with this change.

The NvisionVLE® Optical Probe is comprised 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 nylon shaft, provided without a 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 K182261. Seeking a more specific intended use for the probe in regards to anatomical location, supported by the Clinical Literature, does not affect the intended use or alter the fundamental scientific technology of the device.

7. Performance data:

No new performance testing is being provided given this 510(k) involves additional specific anatomical locations only and does not involve a physical change to the device. The NvisionVLE® Imaging System Low-profile Optical Probe continues to comply 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

8. Clinical Testing

A systematic literature review of the clinical utility of OCT in the pancreatico-biliary system was performed and resulted in multiple studies. To support a determination of substantial equivalence, we have specifically evaluated two (n=2) studies that used the subject device within the biliary and pancreatic ducts. A summary of these studies is shown in the table below.

Summary of Clinical Studies in Literature

Author	Study type/ Objective	Anatomic location / Procedure	Study size (patients)	Histology correlation to image	Adverse events	Conclusion
Corral 2018	Ex vivo: Correlation of OCT images with tissue microstructure of the biliary and pancreatic ducts	Biliary and pancreatic duct within surgical specimens	25	Yes	None	Image features were identified that correlated to tissue-microstructure
Tyberg 2018	In vivo: Feasibility of using OCT to evaluate biliary and pancreatic structures	Biliary and Pancreatic duct within an ERCP procedure	10	No	None	In vivo imaging was successfully completed with no complications and image features were identified that correlated to tissue-microstructure

Within these 2 studies several image features were reported in the OCT images. These included visualization of the layering structure, thickness and morphology of the layering structure as well as the surface intensity. The studies cited demonstrate that OCT imaging is feasible within the pancreatico-biliary system and may be used as a tool to help clinicians evaluate the tissue micro-structure.

In a total of 10 patients involved in the in vivo studies, no OCT-related complications were reported and the data supports that OCT is safe to use during endoscopic retrograde cholangiopancreatography (ERCP) procedures.

These results support the safe and effective use of OCT imaging for aiding a physician to further evaluate tissue regions of interest in the pancreatico-biliary system.

9. Substantial Equivalence Conclusion

The NvisionVLE Low-profile Optical Probe has the same intended use, principles of operation, and technological characteristics as the predicate device.

The additional specific anatomical locations being sought with this 510(k), specific to the Low-profile optical probe, raise no new questions of safety or effectiveness. No new risks are introduced not normally associated with the general use of the device.

The Clinical Literature demonstrates that the NvisionVLE® Imaging System Low-profile Optical Probe, for the additional specific anatomical location of the pancreatico-biliary system, is as safe and effective as the predicate device and is therefore considered substantially equivalent.