DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 6, 2015

Ninepoint Medical Incorporated
Mr. Scott Blood
Senior Director, Quality and Regulatory Affairs
One Kendall Square, Suite B7501
Cambridge, Massachusetts, 02139

Re: K143678
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: January 7, 2015
Received: January 8, 2015

Dear Mr. Blood:

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.

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

Section 6
Statement of Indications for Use

510(k) Number (if known): This application K143678

Device Name: ***Nvision VLE Imaging System***

Indications for Use: *The Nvision VLE 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)

Special 510(k) Summary

1. Basic Information-Submitter:

510(k) Owner:	NinePoint Medical Inc.
Address:	One Kendall Square, Suite B7501 Cambridge, MA 02139 (617) 250-7190 (main number) (617) 250-7199 (fax)
Official Contact:	Scott Blood Sr Director, Quality and Regulatory Affairs (617) 250-7143 (617) 250-7199 (fax) sblood@ninepointmedical.com
Date Summary Prepared:	22 December 2014

2. Device Name:

Trade Name: *NvisionVLE™ Imaging System*
Common Name: Optical Coherence Tomography Imaging System/Optical Frequency Domain Imaging
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, K120800

4. Device Description:

The NinePoint Medical *NvisionVLE™ Imaging System* is a general imaging system comprised of the *NvisionVLE™ Console*, *NvisionVLE™ Optical Probe* and the *NvisionVLE™ Inflation Accessory Kit*.

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.

6. Technological Characteristics:

   The NinePoint Medical *NvisionVLE™ Imaging System* cleared under K120800 consists of the *NvisionVLE™ Console*, the *NvisionVLE™ Catheter* (marketed as the *NvisionVLE™ Optical Probe*) and the *NvisionVLE™ Inflation Accessory Kit.*

   The subject of this Special 510(k) submission is device enhancements to the *NvisionVLE™ Catheter* only.

   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 the optical signal and detects the reflected optical signal for image reconstruction of the targeted tissue.

   The guide sheath is a coaxially-designed balloon sheath. The sheath is composed of a PET balloon and a nylon shaft. 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 K120800. Both devices incorporate balloon guide sheaths and torque shaft-based optical probe subassemblies.

   The following proposed enhancements address vibration and friction that occur while the system is imaging:

   1) Adding an alignment spring to aid and improve the efficiency of the assembly of the optical probe subassembly when attaching the distal stainless steel hypotube to the torque coil.

   2) Identified a torsionally-stiffer torque coil while maintaining identical dimensional and operating characteristics. Improved device trackability

and durability by reducing optical signal disruption and incomplete imaging in tortuous anatomy.

3) Added a thin-walled polymer bearing tube over the torque coil subassembly component of the *NvisionVLE™ Optical Probe*. Improves vibrational and frictional properties of torque coil.

These enhancements do not affect the intended use or alter the fundamental scientific technology of the device and do not result in any updates to the Risk Management Plan.

The modifications are designed to better absorb the vibrational and friction forces in tortuous anatomies and reduce the stress on the optical fiber. These enhancements will improve the durability of the optical probe and meet the physician's needs over a range of esophageal anatomies.

7. Performance data:

A test fixture, Figure 1, was used to evaluate the performance of the current legally marketed device, K120800, versus the device which is the subject of this submission. The testing simulated the probe motion during imaging. All devices were tested through a series of increasing tortuosity until failure occurred.

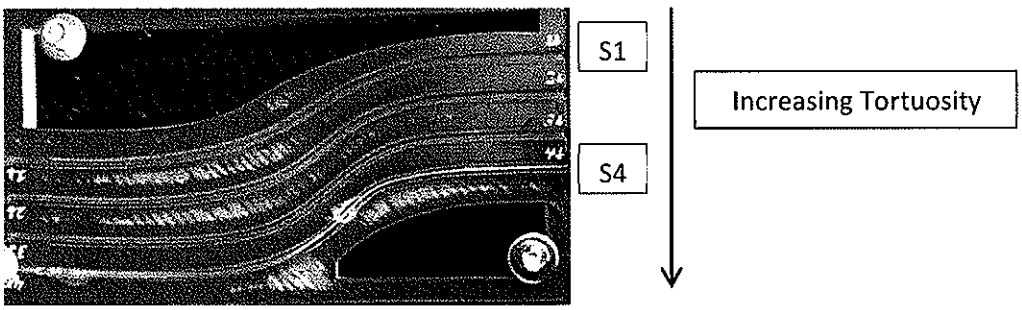

Figure 1: Test Fixture

Failure is defined as the binding of the torque coil during use, resulting in the fracture of the optical fiber and failure to transmit signal. During imaging in some tortuous anatomy, vibration and friction forces are exerted on the optical probe and can stress the optical fiber and induce cracks and breaks. There is no increased risk to the patient when this occurs as the optical fiber is completely encased in the optical probe subassembly and Optical Probe sheath. The following tables summarize the results:

Table 1: Initial engineering test samples

	Tortuous Curve 1	Tortuous Curve 2	Tortuous Curve 3	Tortuous Curve 4
K120800 Controls				
Sample 1	Fail			
Sample 2	Fail			
Sample 3	Fail			
Sample 4	Fail			
Sample 5	Fail			
Proposed Enhancements				
Sample 1	Pass	Pass	Pass	Pass
Sample 2	Pass	Pass	Pass	Pass
Sample 3	Pass	Pass	Pass	Pass
Sample 4	Pass	Pass	Pass	Pass
Sample 5	Pass	Pass	Pass	Pass

Table 2: Manufacturing build samples

	Tortuous Curve 1	Tortuous Curve 2	Tortuous Curve 3	Tortuous Curve 4
K120800 Controls				
Sample 1	Fail			
Sample 2	Fail			
Sample 3	Pass	Fail		
Sample 4	Fail			
Sample 5	Fail			
Sample 6	Fail			
Sample 7	Fail			
Sample 8	Fail			
Sample 9	Pass	Fail		
Sample 10	Fail			
Proposed Enhancements				
Sample 1	Pass	Pass	Pass	Pass
Sample 2	Pass	Pass	Pass	Pass
Sample 3	Pass	Pass	Pass	Pass
Sample 4	Pass	Pass	Pass	Pass
Sample 5	Pass	Pass	Pass	Pass
Sample 6	Pass	Pass	Pass	Pass
Sample 7	Pass	Pass	Pass	Pass

In summary 87% (13/15) of control samples resulted in fiber failure in the least tortuous curve and 13% (2/15) of samples resulted in fiber failure in the

second least tortuous curve. 100% (13/13) of enhanced probe samples passed the most tortuous curve.

8. 510(k) Summary:

NinePoint Medical Inc. has demonstrated that the *NvisionVLE™ Imaging System* is substantially equivalent to the predicate device listed above.