NinePoint
MEDICAL

K 120 800

One Kendall Square, Suite B7501
Cambridge, Massachusetts 02139
ninepointmedical.com

510(k) Summary

APR 2 5 2013

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:	Cindy Domecus, R.A.C. (US & EU) Principal, Domecus Consulting Services LLC Consultant to NinePoint Medical, Inc. (650) 343-4813 (650) 343-7822 (fax) DomecusConsulting@comcast.net
Date Summary Prepared:	March 15, 2012

2. Device Name:

Trade Name: *Nvision VLE 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 Device:
Nvision VLE Imaging System, K112770

4. Device Description:

NinePoint
MEDICAL

One Kendall Square, Suite B7501
Cambridge, Massachusetts 02139
ninepointmedical.com

The NinePoint Medical *Nvision VLE Imaging System* is a general imaging system comprised of the *Nvision VLE Console*, *Nvision VLE Catheter* and the *Nvision VLE Inflation Accessory Kit.*

5. Indications for Use Statement:

   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.

6. Technological Characteristics:

   Optical coherence tomography (OCT) is an imaging technique analogous to ultrasound; however, instead of producing an image from the scattering of sound waves, it utilizes optical scattering based on differences in tissue composition to form two-dimensional images. OCT systems use the principles of low coherence interferometry to generate high-resolution images of tissue microstructures. Interferometry and OCT enable the measurement of the optical back-reflected signals, and therefore the morphology of the internal microstructures can be determined by the back-reflected signal from the different depths of the tissue.

The *Nvision VLE Imaging System* uses a derivative of OCT utilizing swept source technology, referred to as SS-OCT or optical frequency domain imaging, OFDI. OFDI is a derivative development of the time-domain OCT imaging modality, which enables high speed, two-dimensional, cross-sectional, real-time imaging.

NinePoint
MEDICAL

One Kendall Square, Suite B7501
Cambridge, Massachusetts 02139
ninepointmedical.com

7. Performance data:

   The NinePoint Medical *Nvision VLE Imaging System* will be tested against and comply with the following voluntary standards:

   IEC 60601-1, General Safety
   IEC 60601-1-2, Electromagnetic Compatibility
   IEC 60601-1-4, Programmable Electrical Medical Systems
   IEC 60601-2-18, Endoscope
   IEC 60601-2-22, Laser Safety
   IEC 60825-1, Laser Safety
   ISO 10993-1, Biological Evaluation of Medical Devices
   ISO 10993-7, Biological Evaluation of Medical Devices, Ethylene Oxide Sterilization residual testing
   ISO 11135-1, Sterilization of Health Care Products, Ethylene Oxide

   In-vitro and clinical testing have been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

8. 510(k) Summary:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ninpoint Medical, Incorporated
% Domecus Consulting Sevices, LLC
Ms. Cindy Domecus, RAC (US & EU)
1171 Barroilhet Avenue
Hillsborough, California 94010

APR 2 5 2013

Re: K120800
Trade/Device Name: Nine Pointe Medical Inc. Nvision VLE Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: NQQ
Dated: March 11, 2013
Received: March 12, 2013

Dear Ms. Domecus:

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.

The Office of select one Device Evaluation or In Vitro Diagnostic Device Evaluation and Safety] 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 provided 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 (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

Indications for Use

510(k) Number: K120800

Device Name: Nine Pointe Medical Inc. 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) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.03.27 17:00:29 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number __K120800_____