

k112770

DEC 16 2011



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

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: 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: 21 September 2011

2. Device Name:

Trade Name: *Nvision VLE Imaging System (OCT)*
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:

Imalux OCT Imaging System – K033783
Imalux OCT Niris System – K042894
Imalux OCT Probe Sheath – K041077
Tomophase OCTIS - K102599

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4. Device Description:

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 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.

All of the predicate OCT systems employ low coherence interferometry as the basis of the system. The systems use broadband optical sources with either superluminescent diodes or swept sources, high dynamic range detection and either fixed or scanning reference arms. The scanned reference arms were utilized in the Imalux, time domain OCT systems, while the advent of fixed reference arm and swept source OCT technology (Tomophase and NinePoint Medical) has permitted high speed and high sensitivity image capability. The Tomophase predicate device (K102599) and the *Nvision VLE Imaging System* use a derivative of OCT utilizing swept source technology, referred to as SS-OCT or optical frequency domain imaging, OFDI. OFDI is a derivative

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development of the time-domain OCT imaging modality, which enables high speed, two-dimensional, cross-sectional, real-time imaging.

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 devices listed above.



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

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NinePoint Medical, Inc.
% Domecus Consulting Services, LLC
Ms. Cindy Domecus
1171 Barroiht Avenue
Hillsborough, California 94010

Re: K112770
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 09, 2011
Received: December 12, 2011

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) 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. 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.

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

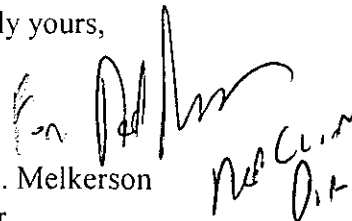
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (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" (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 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". To the right of the signature, there is a handwritten note that says "Melkerson" and "D.H." below it.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112770

**Section 5
Indications for Use Statement**

510(k) Number (if known): This application K112770

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 by providing two-dimensional, cross sectional, real-time depth visualization.

Prescription Use AND/OR Over-the-Counter Use

(Part 21 CFR 801 Subpart D)
Subpart C)

(21CFR 807

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MDM

(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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