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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:	April 12, 2012

2. Device Name:

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

Nvision VLE Imaging System – K112770

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.*

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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:

The technological characteristics of this device are identical to the predicate device cleared under K112770. Both devices incorporate balloon guide sheaths made of identical materials and construction. The subject of this application is a labeling change only, to increase the inflation pressure from 5 psi to a maximum of 30 psi.

7. Performance data:

Burst pressure testing of the balloons as manufactured was performed. Samples from two balloon manufacturing lots were characterized and the burst pressure performed.

The results of the burst testing when analyzed using a one-sided limit statistical test show that the cleared product has minimum burst pressure of approximately 64.8 psi. The subject of this application is a labeling change only to increase the inflation pressure from 5 psi to a maximum of 30 psi, greater than 2x less than the minimum burst pressure.

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 Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 25 2012

NinePoint Medical, Incorporated
% Domecus Consulting Services, LLC
Ms. Cindy Domecus, R.A.C. (US & EU)
Principal, Domecus Consulting Services, LLC
Consultant to NinePoint Medical, Incorporated
1171 Barroihet Avenue
Hillsborough, California 94010

Re: K121195
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: June 26, 2012
Received: June 27, 2012

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 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,

Erin D Keith

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

Enclosure

Section 6
Indications for Use Statement

510(k) Number (if known): This Application

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 ___ 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)

Division Sign-Off)
vision of Surgical, Orthopedic,
d Restorative Devices

(k) Number K121195