APR 0 1 2013

510(k) Summary for the NMI Coaxial Microintroducer Set

Date prepared: 19-October-2012

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Michael Hanley
Specialist, Global Regulatory Affairs
508-263-9714

Wanda Carpinella
Director, Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name:	NMI Coaxial Microintroducer Set
Common/Usual name:	Vessel Dilator / Introducer Sheath
Classification:	Class II-21CFR§870.1310-ProCode: DRE
Classification Name:	Vessel dilator for percutaneous catheterization

D. Predicate Device(s)

Predicate Name:	Vaxcel™ Mini-Stick Coaxial Dilator Set
Predicate 510(k):	K974640

E. Device Description

NMI Coaxial Microintroducer Sets are offered with a 21 gauge needle (4 CM or 7 CM length with or without Echogenic tip), different guidewire configurations (0.018" stainless steel wire body or a Nitinol wire body and with or without Radiopaque tip), and a sheath and dilator assembly (4F X 10 CM regular or stiff, 5F X 10 CM regular or stiff, and 5F X 15 CM stiff), enable users to gain vascular access.

F. Intended Use

The NMI Coaxial Microintroducer Set is used for the percutaneous introduction of a guidewire into the vascular system.

G. Technological Characteristics

The proposed device has similar materials, design and components and technological characteristics as predicate.

H. Performance Data

The proposed Coaxial Microintroducer Set is substantially equivalent to the specified predicate device based on a comparison of technological characteristics and the results of non-clinical test performed in accordance with ISO 11070: *Sterile, Single-Use Intravascular Catheter Introducers*:1999 and ISO 594-2: *Conical Fittings 6% (Luer) Taper for Syringes, Needles, Certain Medical Equipment - Part 2* (1998), which included:

- Tensile Testing
- Leak Testing
- Radiopacity Testing

- Dimensional verification
- Compatibility Testing
- Luer performance
- Biocompatibility per ISO 10993-1

I. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

April 1, 2013

Navilyst Medical, Inc.
Wanda Carpinella
26 Forest Street
Marlborough, MA 01752 US

Re: K123445
Trade/Device Name: NMI Coaxial Microintroducer set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: March 4, 2013
Received: March 12, 2013

Dear Ms. Carpinella:

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.htmfor 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,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if Known): K123445

Device Name: NMI Coaxial Microintroducer Set

Indications for Use:

The NMI Coaxial Microintroducer Set is used for the percutaneous introduction of a guidewire into the vascular system.

Prescription Use (21 CFR 801 Subpart D)	☒	And/Or	AND/OR Over-The-Counter Use: (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)

Bram D. Zuckerman
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