

AUG 19 2011

510(k) SUMMARY**Date Prepared:** August 17, 2011**A. Sponsor**

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Wanda Carpinella
Sr. Manager Global Regulatory Affairs
508-658-7929

Lorraine M. Hanley
Vice President, Global Regulatory Affairs
508-658-7945

C. Device Name

Trade Name:	NMI MC
Common/Usual name:	Microcatheter
Classification Name:	Diagnostic Intravascular Catheter 21 CFR §870.1200, ProCode DQO
Classification	Class II

D. Predicate Device(s)

Trade Name/510(k) Notification:	Boston Scientific Renegade Hi-Flo Microcatheter K000177
	Boston Scientific Renegade STC Microcatheter K023861

E. Device Description

The proposed MC is offered in two French size configurations. The first configuration has an outside diameter of 3.0F/2.8F (tapers proximally to distally) and has a nominal inside diameter of 0.027" along the entire catheter length. The second configuration has an outside diameter of 3.0F/2.4F (tapers proximally to distally) and has a nominal inside diameter of 0.021" along the entire catheter length.

Both MC configurations consist of a shaft and proximal hub assembly. The radiopaque shaft transitions from a stiffer proximal region to a flexible 30cm distal end. A radiopaque marker is located 1mm from the catheter's distal end to identify the location of the distal tip under fluoroscopic visualization. The distal end of the catheter's outer surface is hydrophilic coated. The microcatheter is provided with a shaping mandrel and a rotating hemostatic valve. The microcatheter kit additionally includes a guidewire, a guidewire insertion tool and a torque device.

F. Intended Use

The NMI Microcatheter is intended for use in small vessels and supraselective anatomy during diagnostic and interventional procedures in the peripheral vasculature. Upon access of the desired region, the microcatheter can be used for the controlled and selective infusion of diagnostic, therapeutic and embolic materials. All products delivered through the microcatheter must be used in accordance with the original manufacturer's instruction for use. The catheter is not intended for use in coronary or neuro-vasculature.

G. Technology Characteristics

The proposed device has similar materials, design and components and technological characteristics as currently marketed microcatheters.

H. Performance Data

The NMI MC is substantially equivalent to the specified predicate device based on comparison of technological characteristics and the results of non-clinical tests, which included:

- Coating performance
- Trackability
- Pressure testing
- Dimensional verification
- Radiopacity
- Kink resistance
- Flow rate
- Tip shapability
- Compatibility tests
- Particulate generation
- 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.



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

Navylist Medical, Inc.
c/o Ms. Wanda Carpinella
26 Forest St.
Marlborough, MA 01752

AUG 19 2011

Re: K112124
Trade/Device Name: NMI Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: 21 July 2011
Received: 25 July 2011

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.

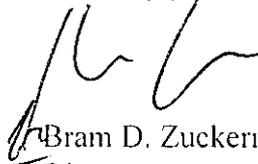
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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.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,



Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

