Navilyst Medical

K101326

510(k) SUMMARY
21 CFR 807.92

Date prepared: August 20, 2010

SEP 2 2010

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Nicholas Condakes Manager, Regulatory Affairs 508-658-7931	Lorraine M. Hanley Director, Global Regulatory Affairs 508-658-7945

C. Device Name

Trade Name:	NMI IC
Common/Usual name:	Intravascular Catheter
Classification Name:	Short and Long-Term Intravascular Catheter 21CFR §880.5970, Class II
Classification Panel:	General Hospital

D. Predicate Device(s)

Trade Name:	Navilyst Medical, Inc. Xcela Power Injectable PICC
Common/Usual name:	Intravascular Catheter
Classification Name:	Short & Long-Term Intravascular Catheter; 21CFR §880.5970, Class II
Premarket Notification(s):	K070002
Classification Panel:	General Hospital

Navilyst Medical, Inc. Central Venous Catheter
Intravascular Catheter
Short & Long-Term Intravascular Catheter; 21CFR §880.5970, Class II
K003839
General Hospital

Bard Power PICC
Intravascular Catheter
Short & Long-Term Intravascular Catheter; 21CFR §880.5970, Class II
K070996, K051991
General Hospital

Bard PowerLine Central Venous Catheter
Intravascular Catheter
Short and Long-Term Intravascular Catheter; 21CFR §880.5970, Class II
K051991
General Hospital

Bard PowerHickman™ Catheter	
Intravascular Catheter	
Short and Long-Term Intravascular Catheter; 21CFR §880.5970, Class II	
K061179	
General Hospital	
Cook Spectrum and Spectrum Glide Central Venous Catheters	
Intravascular Catheter; 21CFR §880.5200, Class II	
K081113	
General Hospital	

E. Device Description

The NMI IC has an open ended lumen with proximally located luer lock adapters(s), extension tube(s) with clamp(s) and suture wing for catheter securement; available in single and multi-lumen configurations; with a reverse tapered shaft to aid in staunching bleeding at the insertion site. The radiopaque catheter is marked with depth indicators along its length. The lumens are differentiated by proximally located colored clamps and luer adapter(s) marked with lumen size. Maximum power injection flow rates are indicated on the clamp(s). The proposed NMI IC will be offered in kits with other legally marketed products.

F. Intended Use

The NMI IC is indicated for short or long-term vascular access (including peripheral) to the central venous system for intravenous therapy, including but not limited to the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring, and for power injection of contrast media.

G. Technology Characteristics

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

H. Performance Data

The NMI IC was assessed in accordance with the following FDA guidance document and international standards:

- EN ISO 10555-1:1996, AMD 1: 1999, AMD 2: 2004, *Sterile, Single use intravascular catheters – Part 1: General Requirements*
- EN ISO 10555-3:1997 COR 2002, *Sterile, Single-Use Intravascular Catheters – Part 3: Central Venous Catheters*
- FDA's "*Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term* Intravascular *Catheters dated March 16, 1995*"
- IEC 60601-2-34:2000-10- *Medical Electrical Equipment - Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment*
- AAMI TIR 9: 1992- *Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring*
- AAMI/ANSI/ISO 10993-1: 2003, *Biological evaluation of medical devices - Part 1: Evaluation and testing*

I. Conclusion

Based on responses to questions posed in FDA's 510(k) Decision Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices

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

Mr. Nicholas Condakes
Regulatory Affairs Manager
Navilyst Medical, Incorporated
26 Forest Street
Marlborough, Massachusetts 01752

SEP 2 2010

Re: K101326
Trade/Device Name: NMI Intravascular Catheter (IC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 11, 2010
Received: August 13, 2010

Dear Mr. Condakes:

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,

for

Anthony D. Watson, B.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101326

Indications for Use

510(k) Number (if Known): K101326

Device Name: NMI Intravascular Catheter (IC)

Indications for Use:

The NMI Intravascular Catheter (IC) is indicated for short or long-term vascular access (including peripheral) to the central venous system for intravenous therapy, including but not limited to the administration of fluids, medications and nutrients, the sampling of blood, for central venous pressure monitoring, and for power injection of contrast media.

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)

Richard C. Chapman 8/31/10
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K101326