K093392

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Navilyst Medical

DEC 31 2009

510(k) SUMMARY

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Wanda Carpinella Acting Project Manager, Global Regulatory Affairs	Lorraine M. Hanley Director, Global Regulatory Affairs

C. Device Name

Trade Name:	To be determined
Common/Usual name:	Percutaneous Drainage Catheter
Classification Name:	FGE-Catheter, Biliary, Diagnostic 21CFR§876.5010, Class II LJE-Catheter, Nephrostomy Pre-Amendment, Unclassified, GBO-Catheter, Nephrostomy, General & Plastic Surgery 21CFR§878.4200, Class I GBX-Catheter, Nephrostomy, General & Plastic Surgery 21CFR§878.4200, Class I

D. Predicate Device(s)

Common/Usual name:	Boston Scientific Corporation Flexima Drainage Catheter
Classification Name:	FGE-Catheter, Biliary, Diagnostic
Regulation Number:	21CFR§876.5010, Class II
Premarket Notification:	K023870 Boston Scientific Corporation Flexima Drainage Catheter FFA-Tube, Drainage, Subrapubic 21CFR§876.5090, Class II K944290 Angiodynamics Total Abscession Biliary Drainage Catheter FGE-Catheter, Biliary, Diagnostic 21CFR§876.5010, Class II K060023

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E. Device Description

The proposed percutaneous drainage catheter consists of a flexible tube with an open distal tip, drainage holes and a lubricious surface. The distal end of the device has either a pigtail or J-Tip configuration. Some catheter models have a radiopaque marker to aid the user in placement. The proximal hub assembly of the device provides a Luer lock hub to allow the user to connect to a fluid collection device. Accessories include a Metal Stiffening Cannula and Plastic Stiffening Cannula and some sets include an additional Trocar.

F. Intended Use

- Multipurpose Drainage Catheters are intended for percutaneous drainage of fluid in the chest, abdomen and pelvis, e.g., abscesses, cysts, biliary, nephrostomy, urinary, pleural empyemas, lung abscess, and mediastinal collections.
- Nephrostomy Drainage Catheters are intended for percutaneous drainage of fluid collections in the urinary system.
- Biliary Drainage Catheters are intended for percutaneous drainage of the biliary tree.

G. Technology Characteristics

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

H. Performance Data

The proposed drainage catheters were tested and compared to predicate devices. Results of this testing demonstrate safety and effectiveness of the proposed device and substantial equivalence. Results of biocompatibility testing performed in accordance with ISO 10993-1 demonstrate the proposed device is acceptable for its intended use.

I. Conclusion

Based on responses to questions posed in the FDA's Decision Making Tree, the proposed devices are substantially equivalent.

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

DEC 31 2009

Ms. Wanda Carpinella
Acting Project Manager, Global Regulatory Affairs
Navilyst Medical, Inc.
26 Forest Street
MARLBOROUGH MA 01752

Re: K093392
Trade/Device Name: Percutaneous Drainage Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: October 29, 2009
Received: October 30, 2009

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.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Abbreviated 510(K)
NMI PDC
29-October-2009

Navilyst Medical

Indications for Use

510(k) Number (if Known): K093392

Device Name: Percutaneous Drainage Catheter

Indications for Use:

Multipurpose Drainage: Catheters are intended for percutaneous drainage of fluid in the chest, abdomen and pelvis, e.g., abscesses, cysts, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collections.

Nephrostomy Drainage: Catheters are intended for percutaneous drainage of fluid collections in the urinary system.

Biliary Drainage: Catheters are intended for percutaneous drainage of the biliary tree.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093392