DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 3, 2017

Navilyst Medical, Inc.
Robin Fuller
Sr. Manager, Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K163452
Trade/Device Name: PICC Maximal Barrier Nursing Kits
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS, PND
Dated: December 8, 2016
Received: December 9, 2016

Dear Robin Fuller:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163452

Device Name
PICC Maximal Barrier Nursing Kits

Indications for Use *(Describe)*

• PICC Maximal Barrier Nursing Kit with BioFlo Hybrid PICC with Endexo Technology and PASV Technology

The PICC Maximal Barrier Nursing Kit with BioFlo Hybrid PICC with Endexo Technology and PASV Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

• PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology

The PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology is indicated for short- or long-term peripheral access 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.

Maximum Power Injection Flow Rate:
• 3F Single Lumen/55 cm 1 mL/sec
• 4F Single Lumen/55 cm 3.5 mL/sec
• 5F Single Lumen/55 cm 5 mL/sec
• 5F Dual Lumen/55 cm 4 mL/sec
• 6F Dual Lumen/55 cm 5 mL/sec
• 6F Triple Lumen/55 – 6 mL/sec

*PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology and PASV Valve Technology

The PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology and PASV Valve Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Maximum Power Injection Flow Rate:
* 3F Single Lumen/55 cm 1 mL/sec
* 4F Single Lumen/55 cm 3.5 mL/sec
* 5F Single Lumen/55 cm 5 mL/sec
* 5F Dual Lumen/55 cm 4 mL/sec
* 6F Dual Lumen/55 cm 5 mL/sec
* 6F Triple Lumen/55 cm 6 mL/sec

*Maximal Barrier Nursing Kit with BioFlo Midline Catheter

The Maximal Barrier Nursing Kit with BioFlo Midline Catheter is indicated for short term access (< 30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and the sampling of blood and blood products. Maximum Power Injection Flow Rates:
* 3F Single Lumen, 20 cm: 2 mL/sec
* 4F Single Lumen, 20 cm: 6 mL/sec
* 5F Single Lumen, 20 cam: 6 mL/sec

* 5F Dual Lumen, 20 cm: 6 mL/sec

*PICC Maximal Barrier Nursing Kit with Xcela Hybrid PICC with PASV Valve Technology

The PICC Maximal Barrier Nursing Kit with Xcela Hybrid PICC with PASV Valve Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valave Technology is 6 mL/sec.

*PICC Maximal Barrier Nursing Kit with Xcela PICC with PASV Valve Technology

The PICC Maximal Barrier Nursing Kit with Xcela PICC with PASV Valve Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

*PICC Maximal Barrier Nursing Kit with Xcela Power Injectable PICC

The PICC Maximal Barrier Nursing Kit with Xcela Power Injectable PICC is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary for the PICC Maximal Barrier Nursing Kit

Date prepared: 2 February 2017

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Robin Fuller
Sr. Manager
Regulatory Affairs
Phone: 508-658-7986

C. Device Name

Trade Name:	PICC Maximal Barrier Nursing Kits
Common Name:	Peripherally Inserted Central Catheter (PICC)
Regulation Number:	21 CFR 880.5970
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	Class II
Product Code:	LJS PND
Classification Panel:	General Hospital Device Panel

D. Predicate Device

Trade Name:	PICC Maximal Barrier Nursing Kits
510(k) Reference:	K142616
Common Name:	Peripherally Inserted Central Catheter (PICC)
Regulation Number:	21 CFR 880.5970
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Regulatory Class:	Class II
Product Code:	LJS PND
Classification Panel:	General Hospital Device Panel
Premarket Notification	K142616

E. Device Description

The PICC Maximal Barrier Nursing Kit is a packaging configuration containing a specified NMI PICC along with (1) procedural aides typically used for PICC placement and (2) *maximal barrier precaution* devices based upon recommendations of Center of Disease Control and Prevention (CDC).

F. Intended Uses

- PICC Maximal Barrier Nursing Kit with BioFlo Hybrid PICC with Endexo Technology and PASV Technology

The PICC Maximal Barrier Nursing Kit with BioFlo Hybrid PICC with Endexo Technology and PASV Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the NMI HPICC III is 6 mL/sec.

- PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology

The PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology is indicated for short- or long-term peripheral access 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.

Maximum Power Injection Flow Rate:

- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 – 6 mL/sec

- PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology and PASV Valve Technology

The PICC Maximal Barrier Nursing Kit with BioFlo PICC with Endexo Technology and PASV Valve Technology is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

Maximum Power Injection Flow Rate:

- 3F Single Lumen/55 cm 1 mL/sec
- 4F Single Lumen/55 cm 3.5 mL/sec
- 5F Single Lumen/55 cm 5 mL/sec
- 5F Dual Lumen/55 cm 4 mL/sec
- 6F Dual Lumen/55 cm 5 mL/sec
- 6F Triple Lumen/55 – 6 mL/sec

- Maximal Barrier Nursing Kit with BioFlo Midline Catheter

The Maximal Barrier Nursing Kit with BioFlo Midline Catheter is indicated for short term access (< 30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and the sampling of blood and blood products. Maximum Power Injection Flow Rates:

- 3F Single Lumen, 20cm: 2 mL/sec

- 4F Single Lumen, 20cm: 6 mL/sec
- 5F Single Lumen, 20cm: 6 mL/sec
- 5F Dual Lumen, 20cm: 6 mL/sec

- PICC Maximal Barrier Nursing Kit with Xcela® Hybrid PICC with PASV® Valve Technology:

The PICC Maximal Barrier Nursing Kit with Xcela Hybrid PICC with PASV Valve Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Non-valved lumens are indicated for central venous pressure monitoring. The maximum power injection flow rate for the Xcela Hybrid PICC with PASV Valve Technology is 6 mL/sec

- PICC Maximal Barrier Nursing Kit with Xcela PICC with PASV Valve Technology:

  The Xcela PICC with PASV Valve Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

- PICC Maximal Barrier Nursing Kit with Xcela Power Injectable PICC:

  The PICC Maximal Barrier Nursing Kit with Xcela Power Injectable PICC is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

Similarities
The proposed PICC Maximal Barrier Nursing Kit contains a PICC catheter packaged with a variety of procedural aide componentry typically used during PICC placement. The proposed PICC indications for use, technological characteristics, materials and operating principles are identical.

Differences
The proposed PICC Maximal Barrier Nursing Kit will have a packaging change. The current outer tray with Tyvek lid will be replaced with a Tyvek/Nylon Pouch. The vendor of several kit accessories will be changed.

H. Performance

The performance evaluation of the PICC Maximal Barrier Nursing Kit new packaging configuration was conducted in accordance with the following national/international standards:

- AAMI/ANSI/ISO 11607-1 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* (2006)
- AAMI/ANSI/ISO 11607-2 *Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes* (2006)

The testing listed in this summary is the result of design verification and validation activities, and risk assessment.

I. Conclusion

Based on results of packaging testing performed according to recognized standards, the proposed PICC Maximal Barrier Nursing Kit is determined to be substantially equivalent to the predicate PICC Maximal Barrier Nursing Kit.