DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 24, 2015

Navilyst Medical, INC.
Ms. Robin Fuller
Sr. Manager, Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K152409
Trade/Device Name: Xcela Power Injectable PICC, Xcela PICC with PASV Valve Technology, and Xcela Hybrid PICC with PASV Valve Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long- term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: August 25, 2015
Received: August 26, 2015

Dear Ms. 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. 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" (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 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 yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K152409

Device Name
Xcela Power Injectable PICC
Xcela PICC with PASV Valve technology
Xcela Hybrid PICC with PASV Valve technology

Indications for Use *(Describe)*
The 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.

Maximum Power Injection Flow Rate

4F Single Lumen - 45 cm length	4 mL/sec	5F Dual Lumen - 45 cm length	5 mL/sec
4F Single Lumen - 55 cm length	3.5 mL/sec	5F Dual Lumen - 55 cm length	4 mL/sec
5F Single Lumen - 55 cm length	5 mL/sec	6F Dual Lumen - 55 cm length	5 mL/sec

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.

The Xcela Hybrid PICC with PASV Valve technology is indicated for short or long-term 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 is 6 mL/sec.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY FOR THE XCELA POWER INJECTABLE PICC, XCELA PICC WITH PASV VALVE AND XCELA HYBRID PICC WITH PASV VALVE

Date prepared: September 24, 2015

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Robin Fuller
Sr. Manager, Regulatory Affairs
508-658-7986

OR

Wanda Carpinella
Director, Regulatory Affairs
508-658-7929

C. Device Name

Trade Name:	Xcela Power Injectable PICC; Xcela PICC w/PASV Valve technology; Xcela Hybrid PICC w/PASV Valve technology
Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Percutaneous, implanted, long-term intravascular catheter 21CFR§880.5970, Class II
Classification Panel:	General Hospital
ProCode	LJS

D. Predicate Device

Common/Usual name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Percutaneous, implanted, long-term intravascular catheter 21CFR§880.5970, Class II
Classification Panel:	General Hospital
Premarket Notification	K150527 (Xcela Power Injectable PICC), K093366 (Xcela PICC w/PASV Valve), K111906 (Xcela Hybrid PICC w/PASV Valve)

E. Device Description

Intended Use

The 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.

Maximum Power Injection Flow Rate	
Description	**Flow Rate**
4F Single Lumen – 45cm length	4 mL/sec
4F Single Lumen – 55cm length	3.5 mL/sec
5F Single Lumen – 55cm length	5 mL/sec
5F Dual Lumen – 45 cm length	5 mL/sec
5F Dual Lumen – 55cm length	4 mL/sec
6F Dual Lumen – 55cm length	5 mL/sec

The Xcela PICC with PASV Valve is technology indicated for short- or long-term 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.

The Xcela Hybrid PICC with PASV Valve technology is indicated for short- or long-term 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 is 6 mL/sec.

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

The only difference compared to the current Xcela Power Injectable PICC, Xcela PICC with PASV Valve and Xcela Hybrid PICC with PASV Valve catheters cleared via **K093366, K111906** and **K150527** is a change of the catheter shaft, luer and suture wing print ink. The proposed device has identical technological characteristics and performance as the predicate intravascular catheters. Both the proposed and predicate devices are, in brief,

- intended for short- or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, and power injection of contrast media.
- available in single and multi-lumen configurations in a wide range of sizes from 3F to 6 F outside catheter diameter;
- rated for maximum power injector settings up to 325 psi
- rated for maximum power injection flow rate up to 6 ml/second based on model; and
- available kitted with a range of procedural accessories for user convenience

F. Performance Data

The impact that the modification has on any associated device risks were evaluated as part of the Risk Analysis (FMEA) activity. There were no modifications of the risk analysis documentation relating to this modification. Verification studies performed focused primarily on the features associated with the change (new catheter shaft, luer and suture wing print ink).

Therefore, product features/specifications affected by this change were tested (catheter shaft print integrity and biocompatibility testing). The following biocompatibility tests were performed:

Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Materials Mediated Pyrogen
Subchronic Toxicity
Subacute Toxicity
Hemolysis – Direct Contact
Hemolysis Extract Method
Coagulation – Partial Thromboplastin Time
In-Vitro Hemocompatibility
Complement Activation
Bacterial Mutagenicity – Ames Assay
In-Vitro Mouse Lymphoma Assay
In-Vivo Mouse Micronucleus Assay
4 Week Implantation
13 Week Implantation
USP Physicochemical Test for Plastics >661<

Since the only change was the ink all other tests that have been performed on the predicate devices are applicable to this device. The testing completed on the predicate devices were as follows:

- Power Injection Flow Rate
- Static Burst Strength
- Multiple Power Injections
- Gravity Flow Rate
- Catheter Length
- Priming Volume
- Dimensional Verification (including ID, OD, Length)
- Catheter Kink/Flex Resistance (including Elongation, Stiffness, Flex Life Strength)
- Alcohol Compatibility
- Catheter Marking & Identification/Radiopacity Testing
- Tensile Testing (of Catheter and Assembly)
- Valve Performance
- Leak Strength
- Aspiration Strength
- Vesicant Testing
- Compatibility Testing

The Xcela Power Injectable PICC, Xcela PICC with PASV Valve and Xcela Hybrid PICC with PASV Valve are substantially equivalent to Navilyst predicate devices based on comparison of technological characteristics and the results of non-clinical tests which included the performance evaluation and biocompatibility testing conducted in accordance with the following FDA guidance documents, international standards, and testing which included:

- EN ISO 10555-1:2009, *Sterile, Single use intravascular catheters – Part 1: General Requirements*
- EN ISO 10555-3:1997 Corrigendum 1:2002, *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*"
- FDA Blue Book Guidance G95-1 "*Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*"

G. 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.