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

May 15, 2015

Navilyst Medical, Inc.
Mr. Brandon Brackett
Specialist II, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K150407
Trade/Device Name: Bioflo Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 12, 2015
Received: February 18, 2015

Dear Mr. Brackett:

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" (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 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)*
Unknown K150407

Device Name
BioFlo Midline Catheter

Indications for Use *(Describe)*

The BioFlo Midline 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. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.

Maximum Power Injection Flow Rate:
-3F Single Lumen, 20 cm: 2 mL/sec
-4F Single Lumen, 20 cm: 6 mL/sec
-5F Single Lumen, 20 cm: 6 mL/sec
-5F Dual Lumen, 20 cm: 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – BioFlo Midline Catheter

Date Prepared: May 12, 2015
Submission Number: K150407

A. Sponsor

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

B. Contact

Brandon M. Brackett
Specialist II, Global Regulatory Affairs
508-658-7984

OR

Wanda Carpinella
Director, Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name:	BioFlo Midline Catheter
Common/Usual Name:	Midline Catheter
Device Classification Name:	Intravascular Catheter
Classification Panel:	General Hospital
ProCode / Regulation Number:	FOZ / 880.5200

D. Predicate & Reference Devices

Predicate 510(k):

Trade Name:	Bard PowerGlide Midline Catheter (**K133856**)
Common/Usual Name:	Midline Catheter
Device Classification Name:	Intravascular Catheter
Classification Panel:	General Hospital
ProCode / Regulation Number:	FOZ / 880.5200

Reference 510(k):

Trade Name:	NMI PICC III and NMI HPICC III (**K131942**)
Common/Usual Name:	PICC
Device Classification Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Classification Panel:	General Hospital
ProCode / Regulation Number:	LJS / 880.5970

E. Device Description

The BioFlo Midline Catheter is a short term (< 30 days) non-valved peripheral venous access devices between 3 to 10 inches in length (8 to 25 cm). Midlines are usually placed in an arm vein such as the basilic, brachial or cephalic and the tip ends below the level of the axillary line. Midline catheters are longer than peripheral IV catheters which are generally 1 to 3 inches long and shorter than peripherally inserted central catheters (PICC) which extend into the superior vena cava. This device provides an alternative to short peripheral IVs and PICCs for certain treatments.

F. Intended Use/Indications for Use

The 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. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L. 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

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

The proposed Navilyst Medical, Inc. BioFlo Midline Catheter is substantially equivalent to the Bard PowerGlide Midline Catheter (**K133856**); and furthermore, contains the identical materials as the referenced Navilyst Medical, Inc. NMI PICC III devices (**K131942**).

Table 1 below compares the key characteristics and components of the proposed and predicate/reference devices, and demonstrates that the proposed BioFlo Midline Catheter and the predicate Bard PowerGlide Midline Catheter are substantially equivalent in regards to Intended Use, key device characteristics, catheter shaft material, range of sizes and lengths, power injectability as well as ProCode and Regulation Number. The proposed device and predicate PowerGlide Midline Catheter differ in that the proposed device is provided with individual catheter placement accessories, whereas the predicate PowerGlide Midline Catheter uses an "Integrated All-In-One". Compatibility testing of the proposed device with insertion accessories demonstrated that the performance was not affected by this minor difference.

Further, the proposed BioFlo Midline Catheter is the same as the referenced NMI PICC III devices, with the exception of catheter indwell time and catheter length. Successful results of bench testing conducted on the proposed device (as described in more detail in Section H below) confirmed that these differences did not raise any new questions of safety and/or effectiveness.

Table 2 contains a side-by-side comparison of the materials of the proposed BioFlo Midline Catheter and referenced NMI PICC III's – both of which are manufactured by Navilyst Medical, Inc. – demonstrating that they are identical. Thus, no new issues of biocompatibility have been identified.

Table 1: Comparison of Key Characteristics of Proposed BioFlo Midline Catheter and Predicate/Reference Devices

Characteristic	Proposed Device: BioFlo Midline Catheter (K150407)	Predicate Device: Bard PowerGlide Midline Catheter (K133856)	Reference Device: NMI PICC III's (K131942)
Intended Use	Short term peripheral venous access device.	Short term peripheral venous access device.	Long term peripheral venous access device.
Catheter Shaft Material	Polyurethane	Polyurethane	Polyurethane
Key Device Components	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Oversleeve, Clamp	Catheter Shaft, Suture Wing, Luer Hub	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Oversleeve
Maximum Power Injection	325 psi	325 psi	325 psi
Catheter Outside Diameter	3F – 5F	2F – 4F	3F – 6F
Catheter Usable Length	10 cm – 20 cm	8 cm – 10 cm	55 cm
Number of Lumens	Single and Dual Lumen	Single Lumen	Single, Dual, and Triple Lumen
X-Ray Confirmation Required	No	No	Yes

Identified as "Midline"	Midline	Midline	PICC
Catheter Shaft Design	Reverse Taper	Reverse Taper	Reverse Taper
ProCode	FOZ	FOZ	LJS
Regulation Number	880.5200	880.5200	880.5970
Placement Technique	Modified Seldinger Technique	Integrated All-In-One Modified Seldinger Technique	Seldinger Techinque; Modified Seldinger Technique

Table 2: Comparison of Materials of Proposed BioFlo Midline Catheter and Reference NMI PICC III's (K131942)		
Device Component	**Proposed Device: BioFlo Midline Catheter (K150407)**	**Reference Device: NMI PICC III's (K131942)**
Catheter Tubing	Polyurethane w/ 30% Barium Sulfate, 2% Endexo, and 0.2% Teal Colorant	**Identical**
Suture Wing	Polyurethane w/ 20% Barium Sulfate	**Identical**
Extension Tubing	Polyurethane	**Identical**
Oversleeve	Polycarbonate Polyurethane w/ 20% Barium Sulfate	**Identical**
Purple Luer	Purple Polyetherimide	**Identical**
White Luer	White Polyetherimide	**Identical**
Ink	MD-1001 No-Tox Medical Device Ink, NT 16 Black w/ MD-1210 Reducer	**Identical**
Clamp	Natural Acetal and Polyurethane	**Identical**

H. Performance Data

The performance evaluation of the proposed BioFlo Midline Catheter included non-clinical bench testing conducted in accordance to the following FDA Guidance Documents and international standards:

- FDA's "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters";
- EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"
- EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters"
- ISO 594-2:1998 – "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings"
- EN ISO 10993-1:2009 – "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"

Bench testing to support substantial equivalence included:

- Power Injection Flow Rate
- Static Burst Strength
- Multiple Power Injections
- Gravity Flow Rate
- Catheter Length
- Priming Volume
- Midline Identification
- 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)
- Compatibility Testing

I. Conclusion

Based upon the above comparisons and successful results of non-clinical bench testing conducted in accordance to the FDA Guidance Documents and international standards listed, as well as responses to questions posed within FDA's 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent to the predicate device.