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 8, 2016

Navilyst Medical, Inc.
Robin Fuller
Sr. Manager, Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 07152

Re: K161866
Trade/Device Name: BioFlo Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: PND
Dated: July 7, 2016
Received: July 7, 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. 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,

Tina Kiang -S

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

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)*
K161866

Device Name
BioFlo Midline Catheter

Indications for Use *(Describe)*
The BioFlo Midline catheter is indicated for short term access 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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for the BioFlo Midline Catheter

Date prepared: 8-September-2016

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. Subject Device

Trade Name:	BioFlo Midline Catheter
Common name:	Intravascular Catheter
Regulation Number	21CFR§880.5200
Regulation Name:	Intravascular Catheter
Regulatory Class:	Class II
Product Code:	PND
Classification Panel:	General Hospital

D. Predicate Device

Trade Name:	BioFlo Midline Catheter
510(k) Reference:	K150407
Common name:	Intravascular Catheter
Regulation Number	21CFR§880.5200
Regulation Name:	Intravascular Catheter
Regulatory Class:	Class II
Product Code:	PND
Classification Panel:	General Hospital

E. Device Description

The BioFlo Midline Catheter is a short term peripheral venous access device 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 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

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

The proposed device is identical in regards to materials, design and components and technological characteristics as the predicate device. The only difference between the proposed device and the predicate device is a change to the Directions For Use (DFU). These changes are noted in Table 1 below.

Table 1: Comparison of DFU changes

DFU Section	**Proposed Device: BioFlo Midline Catheter**	**Predicate Device: BioFlo Midline Catheter (K150407)**
Intended Use/Indications For Use	The BioFlo Midline is indicated for short term access 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 Rate • 3F Single Lumen/20 cm –	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 BioFlo Midline catheters include continuous vesicant therapy, parenteral nutrition,

	2mL/sec • 4F Single Lumen/20 cm – 6 mL/sec • 5F Single Lumen/20 cm – 6mL/sec • 5F Dual Lumen/20 cm – 6mL/sec	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 – 2mL/sec • 4F Single Lumen/20 cm – 6 mL/sec • 5F Single Lumen/20 cm – 6mL/sec • 5F Dual Lumen/20 cm – 6mL/sec
Warnings	Therapies not appropriate for BioFlo Midline Catheters include those therapies requiring central venous access.	Therapies not appropriate for BioFlo Midline Catheters include: • Continuous vesicants • * parenteral nutrition • * solutions with pH < 5 and > 9 • * solutions > 600 mOsmL

Consistent with the Infusion Nurses Society Standards Practice (INS) 2011, the BioFlo Midline Catheter DFU lists out the therapies not appropriate for Midline Catheters under the Indications for Use and Warnings sections. In the INS 2011 version under the section on Midline catheters it states:

"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 osmolality greater than 600 mOsm/L".

Since the original 510(k) submission was concurred (K150407) the INS Standards of Practice has been revised (2016). In the INS 2016 version they have removed reference to infusates with pH less than 5 or greater than 9 and increased the infusates with osmolality from greater than 600 mOsm/L to greater than 900 mOsm/L. In order to not have to update the DFU each time the INS standard changes, we are proposing to change this information in the DFU to refer to the standards of practice. This is similar to the DFU of another Midline Catheter, the Bard PowerGlide Midline catheter (K133856). The Bard PowerGlide Catheter does not refer to therapies not appropriate and the Warning section does not list out therapies not appropriate but rather, refers to those therapies requiring central venous access and refers to standards of practice. The change being made to the BioFlo Midline Catheter DFU would be the same as the Bard PowerGlide Midline DFU.

The change in the Directions for Use does not change the intended use of the device which is to be used 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. The change to the DFU is within an approved set of indications and does not affect the safety or effectiveness of the device.

H.Performance Data

There was no performance testing required due to the DFU change. Performance testing of the predicate 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 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

F. Conclusion

Based on the proposed device having identical materials, design and components and technological characteristics as the predicate device and the same or similar Intended Use as the predicate device the proposed device is determined to be substantially equivalent to the predicate device.