December 16, 2025

Spectrum Vascular
Sharon Klugewicz
Chief Operating Officer/SVP Regulatory Affairs
50 Main St.
Suite 1000
White Plains, New York 10606

Re: K252373
Trade/Device Name: BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve Technology; BioFlo PICC with ENDEXO Technology and PASV Valve Technology; BioFlo PICC with ENDEXO Technology; BioFlo Midline Catheter; Xcela Power Injectable PICC; Xcela PICC with PASV Valve Technology; Xcela Hybrid PICC with PASV Valve Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS, PND
Dated: November 13, 2025
Received: November 13, 2025

Dear Sharon Klugewicz:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

DAVID WOLLOSCHECK -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252373

Device Name
BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve Technology; BioFlo PICC with ENDEXO Technology; BioFlo PICC with ENDEXO Technology and PASV Valve Technology; BioFlo Midline Catheter; Xcela Hybrid PICC with PASV Valve Technology; Xcela PICC with PASV Valve Technology; Xcela Power Injectable PICC

Indications for Use *(Describe)*

BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve Technology
The BioFlo Hybrid PICC with ENDEXO 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. 6F catheter is indicated for patients weighing >10 kg.
Maximum Power Injection Flow Rate:
• 6F Triple Lumen / 55 cm - 6 mL/sec

BioFlo PICC with ENDEXO and PASV Valve Technology
The BioFlo PICC with ENDEXO 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. 6F catheter is indicated for patients weighing >10 kg.

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

BioFlo PICC with ENDEXO Technology
The 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, nutrients; the sampling of blood; for central venous pressure monitoring and for power injection of contrast media. 6F catheter is indicated for patients weighing >10 kg.

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

BioFlo Midline Catheter
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.

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

Xcela Power Injectable PICC
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. 6F catheter is indicated for patients weighing >10 kg.
Maximum Power Injection Flow Rate:
• 4F Single Lumen/45 cm - 4 mL/sec
• 4F Single Lumen/55 cm - 3.5 mL/sec
• 5F Single Lumen/55 cm - 5 mL/sec
• 5F Dual Lumen/45 cm - 5 mL/sec
• 5F Dual Lumen/55 cm - 4 mL/sec
• 6F Dual Lumen/55 cm - 5 mL/sec

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. 6F catheter is indicated for patients weighing >10 kg.

Xcela Hybrid PICC with PASV Technology
The 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. 6F catheter is indicated for patients weighing >10 kg.

Maximum Power Injection Flow Rate:
• 6F Triple Lumen/55 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.

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510(k) SUMMARY - K252373

1. SUBMITTER INFORMATION

Applicant:	Spectrum Vascular
Contact:	Sharon Klugewicz
Phone:	516-425-4446
Email:	sklugewicz@spectrumvascular.com
Address	50 Main Street, Suite 1000 White Plains, NY 10606

2. CORRESPONDENT INFORMATION

Contact:	Sharon Klugewicz
Title:	Sr. VP, Quality and Regulatory Affairs
Firm:	Spectrum Vascular

3. DATE PREPARED: DECEMBER 8, 2025

4. DEVICE INFORMATION

Trade Name:	BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve Technology BioFlo PICC with ENDEXO Technology BioFlo PICC with ENDEXO Technology and PASV Valve Technology BioFlo Midline Catheter Xcela Hybrid PICC with PASV Valve Technology Xcela PICC with PASV Valve Technology Xcela Power Injectable PICC
Common Name:	Peripherally Inserted Central Catheter (PICC)
Regulation Number:	21 CFR 880.5970
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Product Code:	LJS, PND
Regulatory Class:	Class II

5. PREDICATE DEVICE INFORMATION

Device Name:	PICC Maximal Barrier Nursing Kits
Common Name:	Peripherally Inserted Central Catheter (PICC)
510(k) Number:	K163452
Manufacturer:	Navilyst Medical, Inc.

The predicate device has not been subject to a design related recall.

6. DEVICE DESCRIPTION

The BioFlo Hybrid PICC with ENDEXO and PASV Valve Technology is a radiopaque, polyurethane catheter with Luer lock hub(s), polyurethane extension tube(s) and suture wing capable of power injection that is available in a triple lumen configuration. The lumens are differentiated by colored Luer lock hubs that indicate lumen size, “No CT” for non-power injectable lumens are indicated on the luer lock hubs. For non-valved lumens, maximum power injection flow rates are indicated on the clamp(s).

The BioFlo PICCs with ENDEXO and PASV Valve Technology are radiopaque, polyurethane catheters with Luer lock hub(s), polyurethane extension tube(s) and suture wing capable of power injection. The catheter is available in single and multi-lumen configurations. The lumens are differentiated by colored Luer lock hubs that indicate lumen size and maximum power injection flow rates or “No CT” for nonpower injectable lumens.

The BioFlo PICC with ENDEXO Technology is a radiopaque, polyurethane catheter with luer lock hub(s), polyurethane extension tube(s) and suture wing. The catheter is available in single, dual and triple lumen configurations. The lumens are differentiated by colored clamps and hubs that indicate lumen size. Maximum power injection flow rates are indicated on the clamp(s).

The BioFlo Midline with ENDEXO Technology is a radiopaque, polyurethane catheter with luer lock hub(s), polyurethane extension tube(s) and suture wing. The catheter is available in single and dual lumen configurations. The BioFlo Midline is clearly labeled on all available catheter surfaces to identify as a MIDLINE versus a traditional PICC. Maximum power injection flow rates are indicated on the clamp(s). The catheter is offered in 3F, 4F, and 5F sizes.

The Xcela Hybrid PICC with PASV Valve Technology is a radiopaque, polyurethane catheter with Luer lock hub(s), polyurethane extension tube(s) and suture wing capable of power injection. The lumens are differentiated by colored Luer lock hubs that indicate lumen size. "No CT” for non-power injectable lumens are indicated on the luer lock hubs. For non-valved lumens, maximum power injection flow rates are indicated on the clamp(s).

The Xcela PICC with PASV Valve Technology is a radiopaque, polyurethane catheter with Luer lock hub(s), polyurethane extension tube(s) and suture wing capable of power injection. The catheter is available in single and multi-lumen configurations. The lumens are differentiated by colored Luer lock hubs that indicate lumen size and maximum power injection flow rates or “No CT” for non-power injectable lumens.

The Xcela Power Injectable PICC is a radiopaque, polyurethane catheter with Luer lock hub(s), polyurethane extension tube(s) and suture wing. The catheter is available in single and dual lumen configurations. The lumens are differentiated by colored clamps and hubs that indicate lumen size. Maximum power injection flow rates are indicated on the clamp(s).

7. INTENDED USE / INDICATIONS FOR USE

7.1. BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve Technology

The BioFlo Hybrid PICC with ENDEXO 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. 6F catheter is indicated for patients weighing >10 kg.

Maximum Power Injection Flow Rate:

- 6F Triple Lumen / 55 cm - 6 mL/sec

7.2. BioFlo PICC with ENDEXO and PASV Valve Technology

The BioFlo PICC with ENDEXO 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. 6F catheter is indicated for patients weighing >10 kg.

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

7.3. BioFlo PICC with ENDEXO Technology

The 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, nutrients; the sampling of blood; for central venous pressure monitoring and for power injection of contrast media. 6F is catheter indicated for patients weighing >10 kg.

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

7.4. BioFlo Midline Catheter

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.

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

7.5. Xcela Power Injectable PICC

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. 6F catheter is indicated for patients weighing >10 kg.

Maximum Power Injection Flow Rate:

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

7.6. 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. 6F catheter is indicated for patients weighing >10 kg.

7.7. Xcela Hybrid PICC with PASV Technology

The 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. 6F catheter is indicated for patients weighing >10 kg.

Maximum Power Injection Flow Rate:

- 6F Triple Lumen/55 cm - 6 mL/sec

7.8. Conclusion

The Intended Use of the subject devices is the same as the intended use of the predicate devices, with the addition of the following: "6F catheter indicated for patients weighing >10 kg." The Indications for Use of the predicate devices (K163452) reference a specific kit configuration ("Maximal Barrier Nursing Kit") at the beginning of each Intended Use/Indications for Use statement in the Instructions For Use (IFU). The reference to this specific kit configuration has been removed from the Intended Use / Indications for Use statement, as the kit configurations are already included under the Device Description in the IFU. All other aspects of the Intended Use / Indications for Use statements remain unchanged. The PICC and Midline catheters remain the same, apart from the changes to the sterilization cycle parameters which are the subject of this 510(k) submission. The kit configurations are consistent with the device description in the IFU and include the exact same PICC or Midline catheters that were included in the predicate device. These changes do not have any impact on the final finished kit or its performance, and as such, do not raise any new concerns of safety or efficacy.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The BioFlo Hybrid PICC with ENDEXO Technology and PASV Valve Technology, BioFlo PICC with ENDEXO Technology, BioFlo PICC with ENDEXO Technology and PASV Valve Technology, BioFlo Midline Catheter, Xcela Hybrid PICC with PASV Valve Technology, Xcela PICC with PASV Valve Technology, and Xcela Power Injectable PICC are identical to the PICC Maximal Barrier Nursing Kits. No changes have been made to the designs of the devices. This 510(k) is submitted to address changes to the sterilization process parameters and location.

Table 1: Device Comparison Table – BioFlo PICC Family

	Subject Device **BioFlo PICC Family**	**Predicate Device** **PICC Family** K163452
Product Code	LJS	LJS
Models	BioFlo Hybrid with ENDEXO & PASV Valve BioFlo with ENDEXO & PASV Valve BioFlo with ENDEXO	BioFlo Hybrid with ENDEXO & PASV Valve BioFlo with ENDEXO & PASV Valve BioFlo with ENDEXO
Outer Diameter (mm)	3F Single lumen – 1.05 mm 4F Single lumen - 1.40 mm 5F Single lumen - 1.70 mm 5F Dual lumen - 1.75 mm 6F Dual lumen – 1.95 mm 6F Triple lumen – 2.20 mm	3F Single lumen – 1.05 mm 4F Single lumen - 1.40 mm 5F Single lumen - 1.70 mm 5F Dual lumen - 1.75 mm 6F Dual lumen – 1.95 mm 6F Triple lumen – 2.20 mm

	Subject Device **BioFlo PICC Family**	**Predicate Device** **PICC Family** K163452
# of Lumens	**PICC with ENDEXO** 3F Single lumen 4F Single lumen 5F Single lumen 5F Dual lumen 6F Dual lumen 6F Triple lumen **PICC with ENDEXO and PASV Valve** 3F Single lumen 4F Single lumen 5F Single lumen 5F Dual lumen 6F Dual lumen 6F Triple lumen **BioFlo Hybrid PICC with ENDEXO and PASV Valve** 6F Triple lumen	**PICC with ENDEXO** 3F Single lumen 4F Single lumen 5F Single lumen 5F Dual lumen 6F Dual lumen 6F Triple lumen **PICC with ENDEXO and PASV Valve** 3F Single lumen 4F Single lumen 5F Single lumen 5F Dual lumen 6F Dual lumen 6F Triple lumen **BioFlo Hybrid PICC with ENDEXO and PASV Valve** 6F Triple lumen
Lumen Gauge	3F single lumen: 20 4F single lumen: 17.0 5F single lumen: 15.5 5F dual lumen: 17.5 (both lumens) 6F dual lumen: 16.5 (both lumens) 6F triple lumen: 16.5 (1 large power injectable lumen) and 19.0 (2 small non-power injectable lumens)	3F single lumen: 20 4F single lumen: 17.0 5F single lumen: 15.5 5F dual lumen: 17.5 (both lumens) 6F dual lumen: 16.5 (both lumens) 6F triple lumen: 16.5 (1 large power injectable lumen) and 19.0 (2 small non-power injectable lumens)
Usable/Effective Length	All models: 55 cm	All models: 55 cm
Lumen Size (mm)	3F Single lumen – 0.6 mm 4F Single lumen - 0.9 mm 5F Single lumen - 1.1 mm 5F Dual lumen -0.8 / 0.8 mm 6F Dual lumen – 0.9 / 0.9 mm 6F Triple lumen – 1.1 / 0.6 / 0.6 mm	3F Single lumen – 0.6 mm 4F Single lumen - 0.9 mm 5F Single lumen - 1.1 mm 5F Dual lumen -0.8 / 0.8 mm 6F Dual lumen – 0.9 / 0.9 mm 6F Triple lumen – 1.1 / 0.6 / 0.6 mm
Priming Volume	3F single lumen: < 0.8 mL 4F single lumen: <1.1 mL 5F single lumen: < 1.2 mL 5F dual lumen: < 1.0 mL 6F dual lumen: <1.1 mL 6F triple lumen: < 0.9 mL (1 large power injectable lumen) and < 0.6 mL (2 small non-power injectable lumens)	3F single lumen: < 0.8 mL 4F single lumen: <1.1 mL 5F single lumen: < 1.2 mL 5F dual lumen: < 1.0 mL 6F dual lumen: <1.1 mL 6F triple lumen: < 0.9 mL (1 large power injectable lumen) and < 0.6 mL (2 small non-power injectable lumens)
Maximum Power Injection Flow Rate	3F Single Lumen - 1 mL/sec 4F Single Lumen - 3.5 mL/sec 5F Dual Lumen - 4 mL/sec 5F Single Lumen - 5 mL/sec 6F Dual Lumen - 5 mL/sec 6F Triple Lumen - 6 mL/sec	3F Single Lumen - 1 mL/sec 4F Single Lumen - 3.5 mL/sec 5F Dual Lumen- 4 mL/sec 5F Single Lumen - 5 mL/sec 6F Dual Lumen - 5 mL/sec 6F Triple Lumen - 6 mL/sec

	Subject Device **BioFlo PICC Family**	**Predicate Device** **PICC Family** K163452
Packaging	Polystyrene tray/Poly pouch	Polystyrene tray/Poly pouch
Sterilization	EtO	EtO
SAL	10^{-6}	10^{-6}

Table 2: Device Comparison Table – BioFlo Midline Catheter

	Subject Device **BioFlo Midline Catheter**	**Predicate Device** **BioFlo Midline Catheter** K163452
Product Code	PND	PND
Models	BioFlo Midline with ENDEXO Technology	BioFlo Midline with ENDEXO Technology
Outer Diameter (mm)	3F Single lumen – 1.02 mm 4F Single lumen - 1.40 mm 5F Single lumen - 1.68 mm 5F Dual lumen - 1.73 mm	3F Single lumen – 1.02 mm 4F Single lumen - 1.40 mm 5F Single lumen - 1.68 mm 5F Dual lumen - 1.73 mm
# of Lumens	3F - Single lumen 4F - Single lumen 5F - Single lumen 5F - Dual lumen	3F - Single lumen 4F - Single lumen 5F - Single lumen 5F - Dual lumen
Lumen Gauge	3F single lumen: 20.0 4F single lumen: 17.0 5F single lumen: 15.5 5F dual lumen: 17.5 (both lumens)	3F single lumen: 20.0 4F single lumen: 17.0 5F single lumen: 15.5 5F dual lumen: 17.5 (both lumens)
Usable/Effective Length	20 cm	20 cm
Lumen Size (mm)	3F Single lumen - 0.6 mm 4F Single lumen - 0.9 mm 5F Single lumen - 1.1 mm 5F Dual lumen - 0.8 / 0.8 mm	3F Single lumen - 0.6 mm 4F Single lumen - 0.9 mm 5F Single lumen - 1.1 mm 5F Dual lumen -0.8 / 0.8 mm
Priming Volume	3F single lumen: 0.43 mL 4F single lumen: 0.52 mL 5F single lumen: 0.57 mL 5F dual lumen: 0.60 mL	3F single lumen: 0.43 mL 4F single lumen: 0.52 mL 5F single lumen: 0.57 mL 5F dual lumen: 0.60 mL
Maximum Power Injection Flow Rate	3F Single lumen - 2 mL/sec 4F Single lumen - 6 mL/sec 5F Single lumen - 6 mL/sec 5F Dual lumen - 6 mL/sec	3F Single lumen - 2 mL/sec 4F Single lumen - 6 mL/sec 5F Single lumen - 6 mL/sec 5F Dual lumen - 6 mL/sec
Minimum Gravity Flow Rate (water)	3F Single Lumen - 512 mL/hr 4F Single Lumen – 1,928 mL/hr 5F Single Lumen – 2, 280 mL/hr 5F Dual Lumen – 1,524 mL/hr	3F Single Lumen - 512 mL/hr 4F Single Lumen – 1,928 mL/hr 5F Single Lumen – 2, 280 mL/hr 5F Dual Lumen – 1,524 mL/hr
Packaging	Polystyrene tray/Poly pouch	Polystyrene tray/Poly pouch

	Subject Device **BioFlo Midline Catheter**	**Predicate Device** **BioFlo Midlline Catheter** K163452
Sterilization	EtO	EtO
SAL	10^{-6}	10^{-6}

Table 3: Device Comparison Table – Xcela PICC Family

	Subject Device **Xcela PICC Family**	**Predicate Device** **Xcela PICC Family** K163452
Product Code	LJS	LJS
Models	Xcela Power Injectable PICC Xcela PICC with PASV Valve Xcela Hybrid PICC with PASV Valve	Xcela Power Injectable PICC Xcela PICC with PASV Valve Xcela Hybrid PICC with PASV Valve
Outer Diameter (mm)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 1.40 mm 4F Single lumen (55 cm): 1.40 mm 5F Single lumen (55 cm): 1.68 mm 5F Dual lumen (45 cm): 1.73 mm 5F Dual lumen (55 cm): 1.73 mm 6F Dual lumen (55 cm): 1.94 mm **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) – 1.05 mm 4F Single lumen (55cm) – 1.40 mm 5F Single lumen (55 cm) – 1.70 mm 5F Dual lumen (55 cm) – 1.75 mm 6F Dual lumen (55 cm) – 1.95 mm 6F Triple lumen (55 cm) – 2.20 mm **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen - 2.20 mm	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 1.40 mm 4F Single lumen (55 cm): 1.40 mm 5F Single lumen (55 cm): 1.68 mm 5F Dual lumen (45 cm): 1.73 mm 5F Dual lumen (55 cm): 1.73 mm 6F Dual lumen (55 cm): 1.94 mm **Xcela PICC with PASV Valve** 3F Single lumen (55 cm)– 1.05 mm 4F Single lumen (55 cm) – 1.40 mm 5F Single lumen (55 cm) – 1.70 mm 5F Dual lumen (55 cm) – 1.75 mm 6F Dual lumen (55 cm) – 1.95 mm 6F Triple lumen (55 cm) – 2.20 mm **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen - 2.20 mm

	Subject Device **Xcela PICC Family**	**Predicate Device** **Xcela PICC Family** K163452
# of Lumens	**Xcela Power Injectable PICC** 4F Single lumen (45 cm) 4F Single lumen (55 cm) 5F Single lumen (55 cm) 5F Dual lumen (45 cm) 5F Dual lumen (55 cm) 6F Dual lumen (55 cm) **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) 4F Single lumen (55 cm) 5F Single lumen (55 cm) 5F Dual lumen (55 cm) 6F Dual lumen (55 cm) 6F Triple lumen (55 cm) **Xcela Hybrid PICC with PASV Valve** 6F Triple Lumen (55 cm)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm) 4F Single lumen (55 cm) 5F Single lumen (55 cm) 5F Dual lumen (45 cm) 5F Dual lumen (55 cm) 6F Dual lumen (55 cm) **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) 4F Single lumen (55 cm) 5F Single lumen (55 cm) 5F Dual lumen (55 cm) 6F Dual lumen (55 cm) 6F Triple lumen (55 cm) **Xcela Hybrid PICC with PASV Valve** 6F Triple Lumen (55 cm)
Lumen Gauge	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 17.0 4F Single lumen (55 cm): 17.0 5F Single lumen (55 cm): 15.5 5F Dual lumen (45 cm): 17.5 (both lumens) 5F Dual lumen (55 cm): 17.5 (both lumens) 6F Dual lumen (55 cm): 16.5 (both lumens) **Xcela PICC with PASV Valve** 3F Single lumen (55 cm)– 20.0 4F Single lumen (55 cm) – 17.0 5F Single lumen (55 cm) – 15.5 5F Dual lumen (55 cm) – 17.5 (both lumens) 6F Dual lumen (55 cm) – 16.5 (both lumens) 6F Triple lumen (55 cm) – 16.5 / 19.0 (1 large power injectable lumen / 2 small non-power injectable lumens) **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen hybrid (55 cm) – 16.5 / 19.0(1 large power injectable lumen / 2 small non-power injectable lumens)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 17.0 4F Single lumen (55 cm): 17.0 5F Single lumen (55 cm): 15.5 5F Dual lumen (45 cm): 17.5 (both lumens) 5F Dual lumen (55 cm): 17.5 (both lumens) 6F Dual lumen (55 cm): 16.5 (both lumens) **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) – 20.0 4F Single lumen (55 cm) – 17.0 5F Single lumen (55 cm) – 15.5 5F Dual lumen (55 cm) – 17.5 (both lumens) 6F Dual lumen (55 cm) – 16.5 (both lumens) 6F Triple lumen – 16.5 / 19.0(1 large power injectable lumen / 2 small non-power injectable lumens) **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen hybrid (55 cm) – 16.5 / 19.0(1 large power injectable lumen / 2 small non-power injectable lumens)
Usable/Effective Length	**Xcela Power Injectable PICC** 4F Single lumen: 45 cm 4F Single lumen: 55 cm 5F Single lumen: 55 cm 5F Dual lumen: 45 cm 5F Dual lumen: 55 cm 6F Dual lumen: 55 cm **Xcela PICC with PASV Valve** 3F Single lumen: 55 cm 4F Single lumen: 55 cm 5F Single lumen: 55 cm 5F Dual lumen: 55 cm	**Xcela Power Injectable PICC** 4F Single lumen: 45 cm 4F Single lumen: 55 cm 5F Single lumen: 55 cm 5F Dual lumen: 45 cm 5F Dual lumen: 55 cm 6F Dual lumen: 55 cm **Xcela PICC with PASV Valve** 3F Single lumen: 55 cm 4F Single lumen: 55 cm 5F Single lumen: 55 cm 5F Dual lumen: 55 cm

	6F Dual lumen: 55 cm 6F Triple lumen: 55 cm **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen: 55 cm	6F Dual lumen: 55 cm 6F Triple lumen:55 cm **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen: 55 cm

	Subject Device Xcela PICC Family	**Predicate Device Xcela PICC Family** K163452
Lumen Size (mm)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 0.9 mm 4F Single lumen (55 cm): 0.9 mm 5F Single lumen (55 cm): 1.1 mm 5F Dual lumen (45 cm): 0.8 mm (both lumens) 5F Dual lumen (55 cm): 0.8 mm (both lumens) 6F Dual lumen (55 cm): 0.9 mm (both lumens) **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) – 0.6 mm 4F Single lumen (55 cm) - 0.9 mm 5F Single lumen (55 cm) – 1.1 mm 5F Dual lumen (55 cm) – 0.8 / 0.8 mm 6F Dual lumen (55 cm) – 0.9 / 0.9 mm 6F Triple lumen (55 cm) – 1.1 / 0.6 / 0.6 mm **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen : 1.1 / 0.6 / 0.6 mm	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 0.9 mm 4F Single lumen (55 cm): 0.9 mm 5F Single lumen (55 cm): 1.1 mm 5F Dual lumen (45 cm): 0.8 mm (both lumens) 5F Dual lumen (55 cm): 0.8 mm (both lumens) 6F Dual lumen (55 cm): 0.9 mm (both lumens) **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) – 0.6 mm 4F Single lumen (55 cm) - 0.9 mm 5F Single lumen (55 cm) – 1.1 mm 5F Dual lumen (55 cm) – 0.8 / 0.8 mm 6F Dual lumen (55 cm) – 0.9 / 0.9 mm 6F Triple lumen (55 cm) – 1.1 / 0.6 / 0.6 mm **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen : 1.1 / 0.6 / 0.6 mm
Priming Volume	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): < 0.9 mL 4F Single lumen (55 cm): <1.0 mL 5F Single lumen (55 cm): < 1.2 mL 5F Dual lumen (45 cm): < 0.9 mL 5F Dual lumen (55 cm): < 1.0 mL 6F Dual lumen (55 cm): < 1.1 mL **Xcela PICC with PASV Valve** 3F Single lumen (55 cm) < 0.8 mL 4F Single lumen (55 cm) <1.1 mL 5F Single lumen (55 cm) < 1.2 mL 5F Dual lumen (55 cm) < 1.0 mL 6F Dual lumen (55 cm) < 1.1 mL 6F Triple lumen (55 cm) < 0.9 mL / < 0.6 mL (1 large power injectable lumen / 2 small non-power injectable lumens) **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen (55 cm): < 0.7 mL / < 0.6 mL (1 large power injectable lumen / 2 small non-power injectable lumens)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): < 0.9 mL 4F Single lumen (55 cm): <1.0 mL 5F Single lumen (55 cm): < 1.2 mL 5F Dual lumen (45 cm): < 0.9 mL 5F Dual lumen (55 cm): < 1.0 mL 6F Dual lumen (55 cm): < 1.1 mL **Xcela PICC with PASV Valve** 3F Single lumen < 0.8 mL 4F Single lumen <1.1 mL 5F Single lumen < 1.2 mL 5F Dual lumen < 1.0 mL 6F Dual lumen < 1.1 mL 6F Triple lumen < 0.9 mL / < 0.6 mL (1 large power injectable lumen / 2 small non-power injectable lumens) **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen (55 cm): < 0.7 mL / < 0.6 mL (1 large power injectable lumen / 2 small non-power injectable lumens)

	Subject Device **Xcela PICC Family**	**Predicate Device** **Xcela PICC Family** K163452
Minimum Gravity Flow Rate (water)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 848 mL/hr 4F Single lumen (55 cm): 848 mL/hr 5F Single lumen (55 cm): 1856 mL/hr 5F Dual lumen (45 cm): 428 mL/hr 5F Dual lumen (55 cm): 428 mL/hr 6F Dual lumen (55 cm): 690 mL/hr **Xcela PICC with PASV Valve** 3F Single lumen (55 cm): 30 mL/hr 4F Single lumen (55 cm): 150 mL/hr 5F Single lumen (55 cm): 240 mL/hr 5F Dual lumen (55 cm): 60 mL/hr 6F Dual lumen (55 cm): 132 mL/hr 6F Triple lumen (55 cm): 132 mL/hr / 30 mL/hr (1 large power injectable lumen / 2 small non-power injectable lumens) **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen: 892 mL/hr / 30 mL/hr (1 large power injectable lumen / 2 small non-power injectable lumens)	**Xcela Power Injectable PICC** 4F Single lumen (45 cm): 848 mL/hr 4F Single lumen (55 cm): 848 mL/hr 5F Single lumen (55 cm): 1856 mL/hr 5F Dual lumen (45 cm): 428 mL/hr 5F Dual lumen (55 cm): 428 mL/hr 6F Dual lumen (55 cm): 690 mL/hr **Xcela PICC with PASV Valve** 3F Single lumen (55 cm): 30 mL/hr 4F Single lumen (55 cm): 150 mL/hr 5F Single lumen (55 cm): 240 mL/hr 5F Dual lumen (55 cm): 60 mL/hr 6F Dual lumen (55 cm): 132 mL/hr 6F Triple lumen (55 cm): 132 mL/hr / 30 mL/hr (1 large power injectable lumen / 2 small non-power injectable lumens) **Xcela Hybrid PICC with PASV Valve** 6F Triple lumen: 892 mL/hr / 30 mL/hr (1 large power injectable lumen / 2 small non-power injectable lumens)
Packaging	Polystyrene tray/Poly pouch	Polystyrene tray/Poly pouch
Sterilization	EtO	EtO
SAL	10^{-6}	10^{-6}

9. KIT CONFIGURATIONS

The subject devices are offered in a variety of kit configurations. Some kit configurations incorporate minor changes to the specific kit components. All changes were evaluated in accordance with the Quality System which assessed any potential impact to the final kit (e.g., packaging, sterilization). Based on this assessment, it was determined that the changes do not have any impact on the final finished kit or its performance, and as such, do not raise any new concerns of safety or efficacy.

10. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility Testing

The medical devices in their final finished form are identical to the predicate devices (K163452) in formulation, processing, sterilization method, and geometry. No other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents). Therefore, no biocompatibility testing was conducted.

Electrical Safety

Not applicable. The device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Electromagnetic Compatibility (EMC)

Not applicable. The device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software

Not applicable. The device contains no software.

Performance Testing

The following performance testing was conducted to validate changes to the sterilization cycle parameters:

- Ethylene Oxide Sterilization Performance Qualification
- Evaluation of ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals

11. CONCLUSION

The results of the performance testing described above demonstrate that the subject devices are substantially equivalent to the predicate devices.