August 20, 2020

Norfolk Medical Products, Inc.
Natan Pheil
Product Development Manager
7350 N. Ridgeway Avenue
Skokie, Illinois 60076

Re: K192291
Trade/Device Name: TidalPort-AP Implantable Apheresis Vascular Access Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: Class II
Product Code: PTD
Dated: July 17, 2020
Received: July 20, 2020

Dear Natan Pheil:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Payal Patel
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192291

Device Name
TidalPort-AP™ Implantable Apheresis Vascular Access Port

Indications for Use *(Describe)*
The TidalPort-AP™ Implantable Apheresis Vascular Access Port is indicated for therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, I.V. fluids, parenteral nutrition solutions, blood, and blood products.

The TidalPort-AP™ Implantable Apheresis Vascular Access Port is indicated for power injection of contrast media. For power injection of contrast media, the maximium recommended infusion rate is 5 mL/s.

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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K192291

510(k) Summary 21 CFR 807.92

TidalPort-AP™ Implantable Apheresis Vascular Access Port

August 17, 2020

5.1 Submitter/Sponsor Information

Submitter Name:	Norfolk Medical Products, Inc.
FDA Establishment Registration Number:	1450392
Address:	7350 N. Ridgeway Skokie, IL 60076
Telephone Number:	(847) 674-7075
Fax Number:	(847) 674-7066
Contact Person:	Natan Pheil, Product Development Manager

5.2 Device Name

Trade Name:	TidalPort-AP™ Implantable Apheresis Vascular Access Port
Common Name:	Subcutaneous implanted apheresis port
Classification Panel:	80 General Hospital
Regulation:	21 CFR 880.5965
Regulation Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Class:	Class II
Product Code:	PTD

5.3 Predicate Device

Device Name:	PowerFlow™ Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex Catheter
Premarket Notification:	K163001
Product Code:	PTD

Predicate Device

Device Name:	Norfolk Medical SportPort™ (now TidalPortt™) Family of Vascular Access Ports
Premarket Notification:	K112713
Product Code:	LJT

5.4 Device Description

The TidalPort-AP™ has one port size (Standard) and one catheter size (9.6F Polyurethane). It is designed to provide repeated access to the vascular system without the need for repeated venipuncture or the daily care of an external catheter. The TidalPort-AP™ is available as a standard profile totally implantable, titanium port-based design and is accessed perpendicularly to the skin like a typical, conventional access port. For the purpose of apheresis, high-flow procedures, it is accessed with using the FDA Cleared 16G or 18G high-flow, non-coring needle Tidal High-Flow Non-coring Needle (K151341).

The TidalPort-AP™ can also be used for routine vascular access infusion or withdrawal using Huber point needle. For power injection infusion procedures, the subject device can be accessed with a power injection rated needle to create a power-injectable system.

The design of the TidalPort-AP™ utilizes a spherical reservoir and an elongated radius contoured septum to achieve the design purpose of creating a port with a smaller reservoir and less clearance volume. The TidalPort-AP™ comes with a number of kit components to aid in the implantation procedure and/or access of the device once implanted. The TidalPort-AP™ and necessary kit components are provided sterile (EtO).

The overall implanted port system consists of three primary components: the titanium port body with a silicone septum, an attachable radiopaque polyurethane catheter, and a catheter lock which secures the catheter to the port body stem. Once implanted, the method of accessing the subject TidalPort-AP™ device is the exact same as the predicate TidalPort™ device. After the implanted device has been identified and access is prepped per institutional policy, the user palpates the uniquely shaped port. Once the port is palpated, providing the location of the septum, the 16G or 18G high-flow needle (K151341) is inserted into the reservoir for apheresis procedure use. After the reservoir floor is reached, the stylet is unlocked and pulled back slightly, and the needle is once again advanced forward until contacting the reservoir floor again. The stylet is then completely removed, leaving the hollow cannula with luer lock fitting in place. After stylet removal, the cannula is attached to the appropriate extension set and secured for the necessary infusion or withdrawal procedure.

The kit components provided to aid in the implantation procedure and/or access of the device once implanted include:

Implantation Placement Kit:
- 1 x TidalPort-AP™ Implantable Apheresis Vascular Access Port

- 1 x Radiopaque Polyurethane Catheter (9.6F)
- 2 x Catheter Securement Boot
- 1 x Syringe, 5cc with Luer Lock
- 1 x Barbed Malleable Tunneler
- 1 x Vein Pick
- 1 x Blunt Flushing Cannula
- 1 x Needleless Injection Site
- 1 x 22G Straight Huber Point Needle w/Luer Lock Connector
- 1 x Safety Scalpel with #11 Blade

Standard Introducer Kit (optional, pouched separately):

- 1 x Syringe, 10cc with Luer Slip
- 1 x 18G x 2.75" Introducer Needle with Echogenic Tip
- 1 x J-Tip Guidewire with Straightener, 0.035-inch OD x 45 cm length
- 1 x Standard Introducer, Peel-Apart Sheath, with VesselDilator

Valved Introducer Kit (optional, pouched separately):

- 1 x Syringe, 10cc with Luer Slip
- 1 x 18G x 2.75" Introducer Needle, Echogenic
- 1 x J-Tip Guidewire with Straightener, 0.035-inch OD x 45 cm length
- 1 x Valved Introducer, Peel-Apart Sheath, with VesselDilator

Tidal High-Flow Needle (pouched separately):

- 1 x 16G x 1" Tidal High-Flow Non-coring Needle

5.5 Indications for Use Statement

The TidalPort-AP™ Implantable Apheresis Vascular Access Port is indicated for therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, I.V. fluids, parenteral nutrition solutions, blood, and blood products.

The TidalPort-AP™ Implantable Apheresis Vascular Access Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

5.6 Technological Characteristics Summary

The proposed device is substantially equivalent to Bard's PowerFlow Implantable Apheresis Port cleared under 510(k) premarket notification K163001 and Norfolk Medical's TidalPort cleared under 510(k) premarket notification K112713. The subject device is designed to be accessed with a 16G or 18G High-Flow, Non-coring Needle (K151341) for apheresis procedures and has a 9.6F catheter intended to provide optimal flow rates for patients requiring therapeutic apheresis.

An Implantable Port System with a silicone septum for access is the primary technological principle for both the subject and predicate devices. Both port systems have the same primary components: a titanium port w/silicone septum, a radiopaque polyurethane catheter, and a catheter securement mechanism that secures the catheter to the port pin.

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Technological Characteristics:

Feature	Subject Device (TidalPort-AP™)	Predicate (PowerFlow)	Predicate (SportPort)	Comparison – same/different
510(k) Number	K192291	K163001	K112713	-
Indications For Use	The TidalPort-AP™ Implantable Apheresis Vascular Access Port is indicated for therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, I.V. fluids, parenteral nutrition solutions, blood, and blood products. The TidalPort-AP™ Implantable Apheresis Vascular Access Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.	The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, I.V. fluids, parenteral nutrition solutions, blood and blood products. The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.	The SportPort™ is indicated for use when the patient requires the following: repeated access to the vascular system for injections, infusion of drugs, administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen. When used with a power injectable needle infusion set, the SportPort™ is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19 or 20 gauge non-coring power injectable needle and 2ml/s with a 22 gauge non-coring power injectable needle.	1. Same except for device name 2. Different
Port Catheter Size	9.6F Polyurethane	9.6F Polyurethane	9.6F Polyurethane	Same
Port Access Device	22, 20, 19, 18, or 16-Gauge Needle	16- or 14-Gauge IV Catheter	22, 20, 19, 18, or 16-Gauge Needle	1. Different 2. Same
Septum	Silicone Septum	Single Layer Valve	Silicone Septum	1. Different 2. Same

Port Entry	Perpendicular with non-coring needle	Angle entry funnel with an introducer needle stop feature for port system access	Perpendicular with non-coring needle	1. Different 2. Same
Long-term Duration of Use	Repeated access to vascular system	Repeated access to vascular system	Repeated access to vascular system	Same
Subcutaneous Implantation	Tunneled and inserted into blood vessel	Tunneled and inserted into blood vessel	Tunneled and inserted into blood vessel	Same
Catheter Insertion Site	External jugular, internal jugular, or subclavian veins	External jugular, internal jugular, or subclavian veins	External jugular, internal jugular, or subclavian veins	Same
Catheter Tip Placement	Lower 1/3 of superior vena cava	Lower 1/3 of superior vena cava	Lower 1/3 of superior vena cava	Same
Catheter Tip	Open ended tip	Open ended tip	Open ended tip	Same
Port Body Materials	Titanium and Silicone	Titanium Covered with Silicone	Titanium and Silicone	Same
Method of Sterilization	EO Gas	EO Gas	EO Gas	Same

The Indication For Use statements between the TidalPort-AP™ and PowerFlow are the same. It differs from the SportPort™ in that the TidalPort-AP™ adds an indication for therapeutic apheresis, and as such, is limited to one port size and one catheter size.

The differences between the TidalPort-AP™ and the Predicate (PowerFlow) relate to the Port Access Device, Septum, and Port Entry. The differences do not impact the safety and effectiveness of the device. For the Port Access Device, 16-Gauge and 18-Gauge needles are used for apheresis today. The silicone septum creates a self-sealing unit and is easy to identify. Finally, the port entry, being perpendicular to the skin, is well-established which makes the TidalPort-AP™ access technique familiar to clinicians. The performance tests conducted below demonstrate that the differences do not raise new or different questions of safety or effectiveness.

5.7 Discussion of Non-clinical Tests

Norfolk Medical develops product specifications based on design input and risk analysis activities related to the intended use of the product. These product specifications are used to create appropriate design verification tests with reference/guidance to established standards (listed below). For this application, the tests conducted were based on the following standards, specifically in reference to septum puncture / port leak information:

- FDA Guidance on 510(k) Submissions for Implanted Infusion Ports, dated October 1990 was used as a reference for the performance testing.
- FDA Guidance on Implanted Blood Access Devices for Hemodialysis
- FDA Guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Device Labeled as Sterile
- FDA Guidance Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance Environment
- FDA Guidance Use of International Standard ISO 10993, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 10555-1:2013 Sterile, single-use intravascular catheters - Part 1: General requirements
- EN ISO 10555-6:2015 Intravascular catheters - Sterile, single use catheters - Part 6: Subcutaneous implanted ports
- BS EN ISO 10993-1:2010 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- BS EN ISO 10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- BS ENISO 11135:2014 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- BS EN ISO 14971:2012 The application of risk management to medical devices
- ISO 11607-1:2010 Packaging for terminally sterilized medical devices Part 1: Materials, sterile barrier systems and packaging systems
- BS ENISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices
- ASTM F67-13(2017) Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
- ASTM F86-13 Standard practice for surface preparation and marking of metallic surgical implants
- ASTM F640-12 Standard test methods for determining radiopacity for medical use

Performance Data:

The following bench tests were performed to evaluate the performance of the TidalPort-AP™ Implantable Apheresis Vascular Access Port:

1. Catheter to Port Connection
2. Catheter Tensile Strength
3. Radiopacity
4. Gravity Flow Rate
5. Port System Burst under Power Injection
6. Stem Tensile Strength
7. Corrosion Resistance
8. Septum Puncture / Port Leak (w/both Huber point and 2-part large bore needles)
9. Port Clearance Volume
10. Power Injection / Multi-Power Injection
11. Simulated Apheresis Testing- comparison to predicate (PowerFlow)
12. Recirculation, Forward and Reverse Flow- comparison to predicate (PowerFlow)
13. Hemolysis, Forward and Reverse Flow- comparison to predicate (PowerFlow)
14. MRI Safety Testing
15. Packaging Ship Testing
16. Pyrogenicity Testing

Biocompatibility:

The biocompatibility assessment was completed and appropriate endpoints conducted in compliance to ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1 - Evaluation and Testing within a Risk Management Process and the FDA Guidance for Industry - Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

5.8 Conclusion

The TidalPort-AP™ Implantable Apheresis Vascular Access Port has met all predetermined acceptance criteria of design verification evaluations through testing examination. Based on the FDA's decision tree, it is concluded through performance testing that the TidalPort-AP™ Implantable Apheresis Vascular Access Port is substantially equivalent to the predicate device.