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

August 20, 2015

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

Re: K151341
Trade/Device Name: Tidal High-Flow Non-coring Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 13, 2015
Received: May 19, 2015

Dear Mr. 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. 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)*
K151341

Device Name

Tidal High-Flow Non-coring Needle

Indications for Use *(Describe)*

The Tidal High-Flow Non-coring Needle is intended for the access of totally implantable vascular access ports (VAPs) to administer I.V. fluids, infusions drugs, and other fluids, and for the administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen

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.

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Section 5

510(k) Summary

Tidal High-Flow Non-Coring Needle

510(k) Summary 21 CFR 807.92

Part I
General Information

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:	Tidal High-Flow Non-coring Needle
Common Name:	Straight Non-coring Needle
Classification Panel:	80 General Hospital
Classification:	21 CFR 880.5570
Class:	Class II
Product Code:	FMI - Needle, Hypodermic Single Lumen,

5.3 Predicate Device Name

Device Name:	Arrow Non-coring Needle
Premarket Notification:	K961088
Device Name:	Norfolk Medical Posi-Grip Needle
Premarket Notification:	K863721

5.4 Reference Device Name

Device Name: Lucent Non-coring Needle Infusion Set (reference device)

Premarket Notification: K111101

5.5 Device Description

The 16Ga and 18Ga Tidal High-Flow Non-coring Needles are an extension of our 19, 20, and 22 gauge non-coring (Huber) Needle line used to access our line of totally implantable access devices. These large gauge non-coring needles incorporate a stylet to render them non-coring. The needle is made from 304 series stainless steel and the hubs are molded from K-Resin and LDPE. All materials are certified USP Class VI and are the exact same materials used to manufacture the products approved under K863721 and K111101. The needles are a disposable product that will be packaged sterile and non-pyrogenic in a single use peel pouch. ETO sterilization will be used. The sterilization will be done in-house using a validated sterilization procedure that is identical to the sterilization method used in previous 510(k) clearances.

5.6 Indications for Use Statement

The Tidal High-Flow Non-coring Needles are intended for the access of totally implantable vascular access ports (VAPs) to administer I.V. fluids, infusions drugs, and other fluids, and for the administration of blood or blood products, and/or withdrawal of blood as part of the therapy regimen.

5.7 Technological Characteristics and Substantial Equivalence

The proposed devices are equivalent to Arrow International's current legally marketed device cleared under 510(k) premarket notification K961088 (cleared on July 2nd, 1996). The difference consists of a different needle size. Whereas K961088 sought clearance for 14G and 16G needles, this application seeks clearance for 16G and 18G needles. The intended use, the basic design, and the function for the proposed devices are equivalent to the predicate device. They differ from the other predicate device, K863721 and the reference device, K111101, in that these large gauge non-coring needles incorporate a stylet rather than a deflected tip to render them non-coring. These non-coring devices (K863621 and K111101) are included, as we believe this application is an extension of K863721. The materials used are identical, and the tests performed on these devices can readily be referenced.

5.8 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
- ISO 10555-6:2015 – Intravascular catheters -- Sterile and single-use catheters -- Part 6: Subcutaneous implanted ports

Performance Data:

The following bench tests were performed to evaluate the performance of the Tidal High-Flow Non-coring Needles:

1. Septum puncture / Port Leak to failure with the 16Ga high-flow, non-coring needles needles (worst case scenario) using a representative sample of ports found in the marketplace
2. Septum Puncture / Port Leak to failure with a 19Ga Huber point needle following 25 punctures with the 16Ga high-flow needle using a representative sample of ports found in the marketplace

The data collected from the non-clinical tests demonstrated that the functionality and performance characteristics of the Tidal High-Flow Non-coring Needles are comparable to the currently marketed needles based on available literature.

Biocompatibility:

The materials used in the Tidal High-Flow Non-coring Needles are regularly used in the medical device industry. These materials have been well characterized chemically and physically in the published literature and have a long history of safe use.

The raw materials that make up device are as follows: 304 Stainless Steel, K-Resin and Low-density Polyethylene (LDPE). These materials comply with biocompatible requirements ISO 10993 and Pharmacopeia E.P/F.U.I/USP.

Referencing the FDA General Program Memorandum-#G95-1, "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," we have been able to assess the biocompatibility

requirements of the Tidal High-Flow Non-coring Needle.

According to the Blue Book Memorandum-#G95-1, attachment C, "Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)'s", the Tidal High-Flow Needle has met the biocompatibility requirements.

5.9 Conclusion

The Tidal High-Flow Non-coring Needles have met all predetermined acceptance criteria of design verification evaluations through testing examination. Based on the FDA's decision tree, it is logically concluded through evidence that the Tidal High-Flow Non-coring Needles are substantially equivalent to the predicate devices listed above in Section 5.3.