DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 31, 2017

ArraVasc Limited
Ms. Carmel Doherty
Design Assurance Engineer
2 Ballybrit Business Park
Galway, Ireland

Re: K172033
Trade/Device Name: Pirouette High Pressure (HP) PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 30, 2017
Received: July 6, 2017

Dear Ms. Doherty:

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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172033

Device Name
Pirouette High Pressure (HP) PTA Catheter

Indications for Use *(Describe)*
Pirouette High Pressure (HP) PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infrapopliteal, renal arteries, Arterio-venous Fistula (AVF) and Arterio-venous Graft (AVG).

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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Section 5.0
510(k) Summary

5.1 Submitter

Submitter Address:	ArraVasc Limited 2 Ballybrit Business Park, Galway Ireland
Phone Number:	+353-91-758939
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Contact Person:	Carmel Doherty
Date Prepared:	24 August 2017

5.2 Device

Device Trade Name:	Pirouette High Pressure (HP) PTA Catheter K172033
Common Name:	OTW PTA catheter
Classification Name:	Peripheral Transluminal Angioplasty Catheter
Classification number:	21 CFR 870.1250
Product code:	LIT
Class:	II
Classification Panel:	Cardiovascular

5.3 Predicate Devices

Predicate:	Mustang Balloon Dilation Catheter Boston Scientific Corporation. 510(K) number: K103751
Reference device:	Pirouette 018 PTA Dilation Catheter ArraVasc 510(K) number: K151153

5.4 Device Description

Device Description: The Pirouette High Pressure (HP) Percutaneous Transluminal Angioplasty (PTA) Catheter Family are standard over the wire (OTW), semi-compliant, coaxial design catheters with a balloon mounted on the distal tip. The distal portion of the catheter has a hydrophilic coating.
The manifold connector and shaft design consists of a guidewire lumen allowing the catheter to track over a guidewire and an inflation lumen, used to inflate and deflate the balloon. Radiopaque markers are positioned on the shaft within the balloon to enable visualisation of the

	catheter/balloon under fluoroscopy. The catheter is compatible with 0.018-inch (0.46 mm) wire guides. The Pirouette High Pressure (HP) PTA Catheter Family includes multiple balloon sizes ranging from 4 to 6 mm in diameter and 20 to 80mm in length. The nominal balloon diameter (mm) and the balloon length (mm) are inscribed on the guidewire hub of the manifold. The effective lengths of the balloon range from 45cm to 75cm.
Physical Description:	High Pressure (HP) Percutaneous Transluminal Angioplasty Catheter (PTA Catheter).

5.5 Indication for use

Indications for Use Statement:	Pirouette High Pressure (HP) PTA Catheter K172033 is intended for balloon dilation of the iliac, femoral, popliteal, infrapopliteal, renal arteries, Arterio-venous Fistula (AVF) and Arterio-venous Graft (AVG).

5.6 Comparison of technological characteristics with the predicate device

Summary of Technological Characteristics	The Pirouette High Pressure (HP) PTA Catheter K172033 incorporates substantially equivalent design, packaging, fundamental technology, materials, manufacturing, sterilization and intended use as those featured in the predicate, Mustang Balloon Dilation catheter. It has the same design, packaging, fundamental technology, materials, manufacturing, sterilization and hydrophilic coating as the reference device, Pirouette 018 PTA catheter.

Table 1 Summary of general and technical characteristics against the predicate devices.

Parameter	Characteristics
Classification	Class II, 21 CFR 870.1250 Same Classification as predicate devices.
Intended Use	Same intended use of balloon dilatation of the iliac, femoral, popliteal, infra-popliteal, renal arteries, Arterio-venous Fistula (AVF) and Arterio-venous Graft (AVG). The Mustang Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.
Balloon material	Similar type of material (Nylon v Nylon-Pebax blend)
Balloon diameter	Comparable range of balloon diameters: 4 – 6 mm
Balloon length	Comparable range of balloon lengths: 20 - 80mm
Nominal pressure (atm)	Pirouette HP PTA Catheter has the same or higher nominal pressure: 12 atm.
Rated burst pressure (atm)	Pirouette HP PTA Catheter has a comparable rated burst pressure: 22 atm (balloon diameter 4.0- 5.0 mm); 20 atm (balloon diameter 6.0mm)
Radiopaque Marker bands	Pirouette HP PTA Catheter has two Markerbands, one at distal and one at proximal side of the balloon, with the same function.
Outer shaft	Pirouette HP PTA Catheter has similar type of material: Polyamide based
Catheter shaft outer diameter	Pirouette HP PTA Catheter has the same diameter or lower: 3.9 – 4.2 Fr
Catheter Usable Lengths (cm)	Pirouette HP PTA Catheter has a comparable range of usable lengths: 45 - 75cm
Recommended Introducer Sheath compatibility	Pirouette HP PTA Catheter has the same size or lower: 4 – 5 Fr
Recommended Guidewire diameter	Pirouette HP PTA Catheter has the same or lower compatibility; maximum 0.018”
Catheter strain relief & manifold material	Pirouette HP PTA Catheter has the same type of material (Polyamide based), with the same function.
Catheter manifold design	Same design, dual lumen Y design, with the same function.
Catheter coating	Pirouette HP PTA Catheter has similar type of coating.
Sterilization Method	Same method; Ethylene Oxide.
Single Use / Reusable	Single Use

5.7 Performance Data

The Pirouette HP PTA Catheter was thoroughly tested on the bench to evaluate and verify that it meets the required performance specifications and to support a determination of substantial equivalence. The bench testing plan was developed with the consideration of the recommendations outlined in the applicable FDA guidance documents, tests recommended in ISO 10555-1, Intravascular catheters- Sterile and single-use catheters - Part 1: General Requirements, and 10555-4, Intravascular catheters- Sterile and single-use catheters - Part 4: Balloon dilatation catheters. Testing performed on the Pirouette included the following:

Non-Clinical Tests:

- Dimensional verification
- Balloon preparation, pushability , trackability, deployment, withdrawal and balloon reinsertion
- Balloon rated burst pressure (RBP)
- Balloon fatigue (repeated balloon inflations)
- Balloon Compliance at nominal and rated burst inflation pressure
- Balloon Inflation/Deflation Time
- Catheter Bond Strength (Tip to balloon, balloon to proximal shaft, shaft to manifold)
- Flexibility and Kink test
- Torque Strength
- Radiopacity
- Coating Integrity
- Particulate evaluation
- Guide wire compatibility
- Introducer sheath compatibility

The results showed that the Pirouette HP PTA Catheter met the pre-determined acceptance criteria.

Biocompatibility Tests:

Per ISO10993-1:2009, *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process,* the Pirouette HP PTA Catheter is classified as an externally communicating device, which contacts circulating blood during a limited contact duration (≤24hours). Biocompatibility testing was not performed directly on the Pirouette HP PTA Catheter. Biocompatibility testing was leveraged from the reference device-Pirouette 018. Biocompatibility testing was conducted on Pirouette 018 per ISO 10993-1:2009.

The test results show that the Pirouette 018 PTA Catheter is biocompatible, and based on their similar characteristics these were leveraged to support the biocompatibility of the Pirouette HP Catheter.

Sterilization, Shelf life tests and Packaging validation:

- EtO sterilzation validation
- EtO/ECH residue determination
- Shelf life testing
- Packaging validation

Test results show that the Pirouette HP PTA Catheter is sterile and sterility is maintained by the packaging during the entire shelf life of the device. From the results it was also concluded that the device meets the criteria for Residual Testing, i.e. EtO/ECH residues.

Clinical Performance Data:

- No clinical studies were performed for the purpose of obtaining safety and effectiveness data.

5.8 Conclusions

The performance testing and comparison tabulated above demonstrates that the Pirouette High Pressure (HP) PTA Catheter K172033 device is substantially equivalent to the predicate devices.

Information contained within this submission demonstrates that the Pirouette HP PTA Catheter:

- Has a legally marketed predicate device;
- Has the same indications for use as the identified predicate device;
- Incorporates similar fundamental technology, and uses accepted scientific methods and international standards to evaluate device safety and effectiveness;
- Demonstrates that the design and performance of the Pirouette HP PTA Catheter has equivalent safety and performance characteristics of predicate device, and does not raise different questions of safety and effectiveness.

Based upon the; intended use, design, performance characteristics, non-clinical performance testing performed, and comparison to legally marketed devices, it is concluded that the Pirouette HP PTA Catheter is appropriate for its intended use, and is substantially equivalent to the predicate device.