DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 30, 2016

ArraVasc Limited
% Patsy J. Trisler, JD, RAC
Qserve Group US, Inc.
5600 Wisconsin Avenue
Chevy Chase, MD 20815

Re: K161427
Trade/Device Name: Pirouette 035
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: July 6, 2016
Received: July 6, 2016

Dear Ms. Trisler:

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" (21CFR 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,

Brian D. Pullin -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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K161427

Device Name
Pirouette 035

Indications for Use *(Describe)*
Piroutte 035 PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal and renal arteries.

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.**

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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# 510(k) Summary

## 5.1 Submitter

| | |
|---|---|
| Submitter Address: | ArraVasc Limited<br>2 Ballybrit Business Park,<br>Galway<br>Ireland |
| Phone Number: | +353-91-758939 |
| Fax Number: | +353-91-758930 |
| Contact Person: | Aoife Donoghue |
| Date Prepared: | 13 June 2016 |

## 5.2 Device

| | |
|---|---|
| Device Trade Name: | Pirouette 035 |
| 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 Device

| | |
|---|---|
| Primary predicate: | Pirouette 018 OTW PTA Catheter<br>ArraVasc Ltd.<br>510(K) number: K151153 |
| Reference Device | Advance 35LP Low Profile PTA balloon Dilation Catheter<br>Cook Inc.<br>510(k) number K132020 |

## 5.4 Device Description

Device Description: The Pirouette 035 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 visualization of the catheter/balloon under fluoroscopy. The catheter is compatible with .035 inch (0.89 mm) wire guides.

The Pirouette 035 PTA Catheter Family includes multiple balloon sizes ranging from 3 to 12 mm in diameter and 20 to 200mm 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 catheter are 75cm and 130cm.

Physical Description: Percutaneous Transluminal Angioplasty Catheter (PTA Catheter).

**Indication for use**

Indications for Use Statement: Pirouette 035 is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal and renal arteries.

### 5.5 Comparison with the predicate device

The Pirouette 035 is substantially equivalent to the predicate device in design, materials, packaging, fundamental scientific technology, manufacturing, sterilization and intended use. The following table provides a summary of general and technical characteristics as compared to the predicate device.

**Table 1 Comparison of Pirouette 035 to Pirouette 018 (predicate)**

| Parameter | Characteristics |
|---|---|
| Classification | Class II, 21 CFR 870.1250<br>Same Classification as predicate devices. |
| Intended Use | Same intended use: balloon dilatation of the iliac, femoral, popliteal and infra-popliteal arteries and renal arteries. |
| Balloon material | Same material |
| Balloon diameter | Comparable range of balloon diameters: 3 – 12 mm versus 2 - 9 mm for the predicate device |
| Balloon length | Comparable range of balloon lengths: 20 – 200 versus 20 - 300mm for the predicate device |
| Nominal pressure (atm) | Same nominal pressure: 8 atm. |
| Rated burst pressure (atm) | Comparable rated burst pressure: 16atm (2.0-5.0mm balloon diameter) / 14atm (6.0mm balloon diameter) / 12atm (7.0-10.0mm balloon diameter) / 10atm (12.0mm) |
| Radiopaque<br><br>Marker bands | Two Markerbands, one at distal and one at proximal side of the balloon, with the same function. |
| Outer shaft | Same material |
| Catheter shaft outer diameter | Comparable catheter diameter: 5.2 Fr – 5.4 Fr versus: 3.6 – 4.2 Fr for the Predicate |
| Catheter Usable Lengths (cm) | Comparable range of usable lengths: 75 cm and 130 cm versus 45 - 150cm for the Predicate device. |
| Recommended Introducer Sheath compatibility | Comparable size: 5 – 7 Fr versus 4 – 5 Fr for the Predicate device. |
| Recommended Guidewire diameter | Maximum 0.035”” versus; maximum 0.018” |
| Catheter strain relief & manifold material | Same material, with the same function. |
| Catheter manifold design | Same design, dual lumen Y design, with the same function. |
| Catheter coating | Same coating. |
| Sterilization Method | Same method; Ethylene Oxide. |
| Single Use / Reusable | Single Use |

### 5.6 Performance Data

As per ArraVasc Risk Analysis procedures, the Pirouette 035 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 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 035 met the pre-determined acceptance criteria. No new safety or effectiveness issues were raised during this testing.

Biocompatibility Tests:

Per ISO10993-1:2009, *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process,* the Pirouette 035 is classified as an externally communicating device, which contacts circulating blood during a limited contact duration (≤24hours). For reason that the Pirouette 035 has the same indication, general design, materials, and packaging, the Biocompatibility tests with the Pirouette 018 were considered valid for the Pirouette 035. Biocompatibility testing with the Pirouette 018 was conducted per ISO 10993-1:2009 were completed and passed:

- MTT Cytotoxicity Study
- ISO Maximization Sensitization Study
- ISO Intracutaneous Study
- ISO Systemic Toxicity Study
- ASTM Hemolysis
- C3a Complement Activation Assay
- SC5b-9 Complement Activation Assay
- ASTM Partial Thromboplastin Time
- In Vivo Thromboresistance Study - Jugular Vein
- Pyrogenicity

Sterilization, Shelf life tests and Packaging validation:

- EO sterilzation validation by an adoption validation using a sub-lethal cycle approach;
- EO/ECH residues of Pirouette 035 were tested;
- Shelf life testing was leveraged from the data on the Pirouette 018;
- Packaging validation was leveraged on the data of the Pirouette 018.

The results show that the Pirouette 035 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. EO/ECH residues.

Clinical Performance Data:

- No clinical studies were performed for the purpose of obtaining safety and effectiveness data.
- The Pirouette 035 has been approved for marketing in the European Union (CE certified) in 2015, and has been marketed in the EU thereafter.

### 5.7 Conclusions

Based upon the intended use, fundamental scientific technology, performance characteristics, non-clinical performance testing, and comparison to legally marketed devices, it is concluded that the Pirouette 035 is appropriate for its intended use, and is substantially equivalent to the predicate device.