



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 22, 2016

ArraVasc Ltd.
Ms. Aoife Donoghue
Regulatory and Design Assurance Manager
2 Ballybrit Business Park
Galway, Ireland

Re: K162316
Trade/Device Name: Pirouette 014
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: October 25, 2016
Received: October 31, 2016

Dear Ms. Donoghue:

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,


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

Indications for Use

510(k) Number (if known)

K162316

Device Name

Pirouette 014

Indications for Use (Describe)

The Pirouette 014 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.

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Submitter:
ArraVasc Ltd.

Pirouette 014
Premarket Notification: Special 510(k)

510(k) Summary

5.1 Submitter

Submitter Address: ArraVasc Limited
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Ireland

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Contact Person: Aoife Donoghue Regulatory & Design Assurance Manager

Date Prepared: 04 Aug 2016

5.2 Device

Device Trade Name: Pirouette 014

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

Predicate: Pirouette 018 OTW PTA Catheter
ArraVasc Ltd.
510(K) number: K151153

Reference Device: Bantam α PTA Catheter
ClearStream Technologies Ltd
510(K) number: K093139

5.4 Device Description

Device Description: The Pirouette 014 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 .014 inch (0.356 mm) wire guides.

The Pirouette 014 PTA Catheter Family includes multiple balloon sizes ranging from 1.25 mm to 4.0 mm in diameter and 15 mm to 300 mm 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 90 cm, 130 cm and 150 cm.

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

5.5 Indication for use

Indications for Use Statement: The Pirouette 014 PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal, and renal arteries.

5.6 Comparison with the predicate device

The Pirouette 014 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 primary predicate device and predicate device.

Table 1 Comparison of Pirouette 014 to Pirouette 018 (Predicate)

Parameter	Characteristics
Classification	Class II, 21 CFR 870.1250 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: 1.25 mm – 4.0 mm versus 2.0 mm – 9.0 mm for the predicate device
Balloon length	Comparable range of balloon lengths: 15 mm – 300 mm versus 20 mm – 300 mm for the predicate device
Nominal pressure (atm)	Same nominal pressure: 8 atm.
Rated burst pressure (atm)	Same rated burst pressure: 16 atm
Radioopaque markerbands	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: 2-7- 3.6 Fr versus: 3.6 – 4.2 Fr for the Predicate
Catheter Usable lengths (cm)	Comparable range of usable lengths: 90 cm - 150 cm versus 45 cm - 150cm for the Predicate device
Recommended Introducer Sheath Size compatibility	Comparable size: 4 Fr versus 4 – 5 Fr for the Predicate device
Recommended Guidewire diameter	Maximum 0.014" 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

5.7 Performance Data

As per ArraVasc Risk Analysis procedures, the Pirouette 014 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 014 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 014 is classified as an externally communicating device, which contacts circulating blood during a limited contact duration (≤ 24 hours). For reason that the Pirouette 014 has the same indication, general design, materials, and packaging, the Biocompatibility tests with the Pirouette 018 were considered valid for the Pirouette 014. 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

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Sterilization, Shelf life tests and Packaging validation:

- EO sterilization validation by an adoption validation using a sub-lethal cycle approach;
- EO/ECH residues of Pirouette 035 (K161427) were tested (largest surface area of Pirouette family, therefore worst case);
- 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 014 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 014 is approved for marketing in the European Union (CE certified).

5.8 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 014 is appropriate for its intended use, and is substantially equivalent to the predicate device.