April 12, 2018

Medtronic Vascular, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K173515
Trade/Device Name: Admiral Xtreme
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 5, 2018
Received: April 6, 2018

Dear Mr. Job:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Kenneth J. Cavanaugh -S

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)*
K173515

Device Name
Admiral Xtreme

Indications for Use *(Describe)*
The Admiral Xtreme PTA balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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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510(k) Summary

This 510(k) Summary is submitted per the requirements of 21 CFR Part 807, Section 807.92.

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Date Prepared: November 6, 2017

Device Information

Trade Name:	Admiral™ Xtreme
Common Name:	PTA Balloon Catheter
Regulation Name:	Percutaneous Catheter
Classification:	Class II
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.1250
Product Code:	LIT

Predicate Device

- Admiral™ Xtreme PTA Balloon Dilatation Catheter (K062809 SE- October 18th, 2006 and K100921 SE- April 30th, 2010)

This predicate device has not been subject to a design-related recall.

Reference Device

- TOTAL across™ (K133539 SE- March 26th,2014)

This reference device has not been subject to a design-related recall.

Device Description

The Admiral Xtreme is an Over the Wire (OTW) Percutaneous Transluminal Angioplasty (PTA) catheter. The device is provided sterile (EtO).

The catheter has a dual-lumen shaft that is branched at the proximal end. One lumen forms the entrance to the central lumen for the guidewire, and the other lumen is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution. The catheter and balloon are designed to reach targeted inflation diameters, depending on the balloon size and defined pressure.

The Admiral Xtreme is compatible with guidewires with a maximum diameter of 0.035" (0.89 mm) and with 5F, 6F or 7F introducer sheaths depending on balloon size. The catheter is provided with a hydrophilic coating and is available in useable catheter lengths of 80, 130 or 150cm.

Balloon sizes range from 3.0mm to 12.0mm in diameter, with balloon lengths from 20mm to 300mm. The balloons reach nominal diameter at 6atm or 8atm (Nominal Pressure) and have Rated Burst Pressure (RBP) of 14atm, 12atm and 11atm depending on the balloon diameter and balloon length.

Indications for Use

The Admiral Xtreme PTA balloon dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The indications for use for the Admiral Xtreme (hereinafter referred to also as "subject device") are the same as the ones of the currently cleared predicate device, Admiral™ Xtreme PTA Balloon Dilatation Catheter (hereinafter referred to as "predicate device").

Technological Characteristics

The overall design and the fundamental scientific technology (operating principle and mechanism of action) of the subject device are substantially equivalent to the currently cleared predicate device. The subject device is designed to improve upon the predicate device and to extend its size matrix. The design improvements on the subject device do not adversely affect the risk profile of the device and do not introduce new additional risks.

The subject device shares the following similarities to the predicate device:

- Similar fundamental scientific technology

- Identical operating principle
- Identical indications for use
- Identical materials except for the connector and the device packaging
- Identical sterilization method and parameters

Differences include:

- Change in the introducer sheath compatibility from 6F (predicate device) to 5F (subject device) for some device sizes
- A modified dual lumen shaft design for some device sizes: this modified shaft has a maximum catheter shaft diameter of 5.3F compared to the 6F of the predicate device
- Addition of 150cm catheter useable length
- Addition of 100mm balloon length
- New design and material for the subject device connector
- New design and materials for the subject device packaging

Comparative performance testing was also conducted with the predicate device. The bench test results demonstrated that the subject device met the acceptance criteria and that the predicate device and the subject device are substantially equivalent with respect to the performance characteristics, with no different questions of safety and effectiveness which arose during the testing.

Summary of Bench Testing

The Admiral Xtreme was thoroughly tested on the bench to evaluate and verify that it meets the required performance specifications. The bench testing plan was developed based on the risk assessment of the device modifications and taking into account the recommendations outlined in the applicable FDA guidance documents and ISO standards.

Testing performed on the Admiral Xtreme device included the following:

- Dimensional Verification
- Balloon Preparation, Deployment and Retraction
- Balloon Rated Burst Pressure (RBP)
- Balloon Fatigue (repeated balloon inflations)
- Balloon Compliance (Diameter vs. Pressure)
- Balloon Inflation/Deflation Time
- Catheter Bond Strength
- Tip Pull
- Flexibility and Kink
- Torque Strength
- Coating Integrity
- Hub Test
- Laser Marking Visual Inspection

- Catheter Burst Pressure
- Catheter Fatigue
- Particulate Evaluation

All the pre-determined acceptance criteria were met and the testing passed.

The radiopacity performance test was leveraged from the predicate device.

Summary of Biocompatibility Testing

The Admiral Xtreme is an externally communicating device, which contacts circulating blood for the limited contact duration (≤24hours).

In accordance with the principles of the ISO 10993-1:2009 *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process* as specified in the FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process "Guidance for Industry and Food and Drug Administration Staff (June 2016)* and FDA guidance *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (Sept 2010),* a biological evaluation was conducted for the subject device in order to detect any potential adverse biological response due to different manufacturing process and different packaging, including these biocompatibility tests:

- Cytotoxicity Study using the ISO MEM Elution Method
- ASTM Hemolysis Study

In addition, an Infrared Spectroscopy Study has been performed.

All the pre-determined acceptance criteria were met and the testing passed.

Biocompatibility testing that were leveraged from the predicate device are the following:

- Cytotoxicity Study using the MEM Elution Method, L929 Mouse Fibroblast Cells
- Maximization Sensitization Test
- Intracutaneous Injection test
- Systemic Injection test
- Rabbit pyrogen test (material mediated)
- In-Vitro Hemocompatibility Assay
- Hemolysis Study (Autian method – indirect contact)
- Plasma Recalcification Time Coagulation Study (Lee and White Coagulation test)

Biocompatibility testing that were leveraged from the reference device are the following:

- Cytotoxicity Study using the ISO MEM Elution Method
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits

- ISO Systemic Toxicity Study in Mice
- USP Pyrogen study - Material mediated
- Bacteria Reverse Mutation Study
- ASTM Hemolysis Study
- C3a Complement Activation Assay
- SC5b-9 Complement Activation Assay
- In-vivo Thromboresistance Study in the Dog, Jugular Vein
- ASTM Partial Thromboplastin time

Assessment of Non-Clinical Performance Data for Equivalence

Performance testing and biological evaluation with biocompatibility testing on the subject device were performed in accordance with the relevant FDA guidance, ISO and ASTM standards. Results from these non-clinical testing demonstrates that the Admiral Xtreme met the pre-determined acceptance criteria. No different questions of safety and effectiveness arose during the testing, showing that the subject device is substantial equivalent to the predicate device.

Results from the comparative performance testing further support the substantial equivalence between the subject device and the predicate device.

Conclusion

Results from the non-clinical performance testing demonstrate that the subject device is substantially equivalent to the predicate device.

In conclusion, Medtronic believes that the subject device (the modified Admiral Xtreme) is substantially equivalent to the predicate device Admiral Xtreme based on the same intended use (including indications for use) and based on the overall design, fundamental scientific technology (operating principle and mechanism of action) and results of performance testing provided in this submission, which show that the subject device performs as well as the predicate device.

Moreover, the subject device does not raise different questions of safety and effectiveness than the predicate device.