



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

July 6, 2015

Abbott Vascular
Shu Chi Hsu
Project Manager, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K151317

Trade/Device Name: Armada 18 PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 19, 2015
Received: June 22, 2015

Dear Shu Chi Hsu:

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 yours,



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)

K151317

Device Name

Armada 18 PTA Catheter

Indications for Use (Describe)

The Armada 18 is indicated to dilate stenosis in femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, the device is also indicated for post-dilatation of balloon-expandable and self-expanding stents.

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.

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510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. Submitter's Name Abbott Vascular
2. Submitter's Address 3200 Lakeside Dr. Santa Clara, CA 95054
3. Telephone (408) 845-1256
4. Fax (408) 845-3743
5. Contact Person Shu Chi Hsu
6. Date Prepared May 14, 2015
7. Device Trade Name Armada 18 PTA Catheter
8. Device Common Name PTA Catheter
9. Device Classification Name Catheter, angioplasty, peripheral, transluminal
(21 CFR 870.1250, LIT)
10. Predicate Device Name Armada 14 PTA Catheter (K102705, cleared on
December 7, 2010)

11. Device Description

The Armada 18 is a 0.018" guide wire compatible and Over-the-Wire catheter used for Percutaneous Transluminal Angioplasty (PTA) procedures. The single-layer balloon is available in lengths of 20 to 200 mm with nominal diameters of 2.0 to 6.0 mm. The catheter shaft has working lengths of 90 or 150 cm.

There are two radiopaque marker bands for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating section of the balloon and help in balloon placement.

An adaption arm is provided on the proximal end of the dilatation catheter to provide access to the inflation lumen and the guide wire lumen. It is designed with a luer-lock fitting for connection with an inflation device. The balloon is inflated using the side port, at which point the balloon expands to a known diameter at specific pressures. The working pressure range for the balloon is between the nominal pressure and the rated burst pressure. All balloons distend to diameters above the nominal diameter when inflated to pressures greater than the nominal pressure.

The Armada 18 PTA Catheter is sterilized with ethylene oxide (EO) and is intended for single use.

12. Indication for Use

The Armada 18 is indicated to dilate stenosis in femoral, popliteal, infra-popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, the device is also indicated for post-dilatation of balloon-expandable and self-expanding stents.

13. Technological Characteristics

Comparison of the new device and predicate device demonstrate that the technological characteristics such as product performance, design (with minor modifications) and indications for use are substantially equivalent to the current marketed predicate device.

14. Performance Data

Performance testing was successfully completed on the Armada 18 PTA Catheter. The following tests were conducted:

- Dimensional Verification
- Catheter Preparation, Delivery, Deployment and Retraction
- Rated Burst Pressure, Rated Burst Pressure - In Stent
- Fatigue, Fatigue - In Stent
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Catheter Tensile Strength
- Flexibility and Kink Test
- Torque Strength
- Particulate Evaluation
- Coating Integrity
- Accelerated Aging

Biocompatibility testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogen, hemolysis, coagulation and complement activation.

15. Conclusions

Test results from the *in vitro* bench testing conducted on the subject device demonstrate that the Armada 18 PTA Catheter met all acceptance criteria and performed similarly to the predicate device and that no new safety or effectiveness issues were raised during the testing program. Therefore, the Armada 18 PTA Catheter may be considered substantially equivalent to the predicate device.