DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 25, 2017

Abbott Vascular
Ms. Kathyrene Logrono
Project Manager, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95054

Re: K172073
Trade/Device Name: Hi-Torque Command 18 Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: July 27, 2017
Received: July 28, 2017

Dear Ms. Logrono:

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 (DICE) 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 (DICE) 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,

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)*
K172073

Device Name
Hi-Torque Command 18 Guide Wire

Indications for Use *(Describe)*
This Hi-Torque Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA) in arteries such as the femoral, popliteal, and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.

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

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) 845-0597
4. Fax	(408) 845-3743
5. Contact Person	Kathyrene Logrono
6. Date Prepared	July 07, 2017
7. Device Trade Name	Hi-Torque Command 18 Guide Wire
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	Hi-Torque Command Guide Wire Family (K122573, cleared on November 20, 2012) Hi-Torque Command 18 Guide Wire (K152404, cleared on September 21, 2015)

11. Device Description

The Abbott Vascular Hi-Torque (HT) Command 18 Guide Wire with hydrophilic coating is a guide wire with a maximum diameter of 0.0180" and is provided in 210 cm and 300 cm lengths.

The Abbott Vascular HT Command 18 Guide Wire consists of a 304V stainless steel proximal core and a nitinol distal core. The distal core is attached to the stainless steel proximal core using a dissimilar metal solid-state resistance weld. The core wire at the tip is flattened to provide optimize flexibility, steering, and tip shaping. There are four nitinol lengths of the HT Command 18 family, each having multiple tip load options. The HT Command 18 has a straight (shapeable) tip.

The distal portion of the wire is covered with a polyurethane jacket and a hydrophilic coating. The proximal section of the wire is coated with polytetrafluoroethylene (PTFE) and a single coat of a silicone-based hydrophobic coating. Brachial and femoral markers are located on the proximal segment of the 210 cm and 300 cm guide wires.HT Command 18

Guide Wire is offered in two (2) packaging configuration options: With Accessory Devices (Torque Device and Guide Wire Introducer) and Without Accessory Devices.

12. Indications for Use

This Hi-Torque Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA) in arteries such as the femoral, popliteal, and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.

13. Technological Characteristics

The new device includes an additional packaging configuration (without accessory devices) and associated labeling changes, alternate packaging pouch from a different supplier, changes to the distal tip design, changes to the distal nitinol core wire and proximal stainless steel wire dimensions, changes to the proximal joint material, and changes to the coating and distal tip flattening process.

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

Hi-Torque Command 18 Guide Wire testing successfully met functional and dimensional acceptance criteria and external requirements.

- Surface Appearance
- Polyurethane Coating
- PTFE Coating
- Tip Appearance
- Outside Diameter
- Hydrophilic Coating Friction Test
- Guide Wire Particulates
- Torsional Wire Strength
- Tip Tensile Strength
- Overall Length
- Proximal Marker Locations
- Dissimilar Metal Weld Strength
- Rotary Bend Strength
- U-Bend Tensile Strength

- Tip Load
- Rotational Accuracy Testing (Torqueability)

Design (minor) changes were deemed non-impactful to biocompatibility as there are no new materials of construction, manufacturing aids, tooling materials and primary packaging materials and sterilization methods. Previous test results showed substantial equivalence to the current marketed predicate devices.

15. Conclusions

Test results from the functional and dimensional testing conducted on the subject Hi-Torque Command 18 Guide Wire met all acceptance criteria and show that it performed similarly to the predicate devices. There were no new safety or effectiveness issues raised during the testing program.

The Hi-Torque Command 18 Guide Wire is substantially equivalent to the predicate devices in regards to the indications for use, materials, fundamental technology, design, performance, biocompatibility, sterilization, and packaging and is safe and effective for clinical use.