



Food and Drug Administration
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September 21, 2015

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

Re: K152404

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: August 24, 2015
Received: August 25, 2015

Dear Dr. 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,

Kenneth J. Cavanaugh -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)

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) 845-1256
4. Fax (408) 845-3743
5. Contact Person Shu Chi Hsu
6. Date Prepared August 24, 2015
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)

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 processed to optimize flexibility, steering, and tip shaping. There are four nitinol lengths of the HT Command 18 family, each having multiple tip load options. HT Command 18 has a straight (shapeable) tip.

The distal portion of the wire is coated 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.

A Torque Device and Guide Wire Introducer are supplied with the wire to facilitate the procedures as physician's aids, if desired.

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

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 Hi-Torque Command 18 Guide Wire. *In vitro* functional bench testing conducted on the subject device included:

- Catheter compatibility,
- Radiopacity,
- Tip tensile strength,
- Torsional wire strength,
- Dissimilar metal weld strength,
- Rotary bend strength,
- Tip load,
- Rotational accuracy,
- Coating adherence and integrity (particulate testing), and
- Friction testing

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

15. Conclusions

Test results from the non-clinical *in vitro* bench testing conducted on the Hi-Torque Command 18 Guide Wire family 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 device in regards to the indications for use, materials, fundamental technology, design, performance, biocompatibility, sterilization, and packaging.