510(k) Summary

JUL - 8 2010

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 Drive, Santa Clara, CA 95054
3. Telephone	(408) 845-0688
4. Fax	(408) 845-3743
5. Contact Person	Laarni Ricafort
6. Date Prepared	June 10, 2010
7. Device Trade Name	Hi-Torque Winn Guide Wire Family
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	HI-TORQUE PROGRESS Guide Wire (K091825, cleared September 25, 2009)

11. Device Description

The Hi-Torque Winn Guide Wire Family is a family of guide wires, designed to provide improved torque response and crossing while maintaining tactile feedback in stenotic vessels. The subject wire is a core to tip design, where the core material runs through the entire length of the wire. This family of guide wires have a maximum diameter of 0.0140" with a stainless steel core and are provided in 190 cm extendable and 300 cm exchange lengths. The distal core segment of the Winn is offered in 5 configurations: Winn 40, Winn 80, Winn 120, Winn 140T and Winn 200T. Each configuration is identical in design except for those design features that impact tip stiffness.

12. Indication for Use

This Hi-Torque Winn guide wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

13. Technological Characteristics

Comparisons of the new and predicate device show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate device.

14. Performance Data

Performance testing was successfully completed on the predicate device, the HI-TORQUE PROGRESS Guide Wire Family. The following performance characteristics were leveraged for the proposed device:

- Tensile Strength (Tip Pulls)
- Torque Strength (Turns to Separation)
- Torqueability (Rotational Accuracy)
- Tip Flexibility
- Friction/Lubricity Test (Pig Aorta)
- Coating Adhesion and Integrity Test (Particulate)
- Biocompatibility
    - Cytotoxicity – ISO Elution Test (MEM Extract)
    - Hemolysis Test – Direct Contact Method
        - Hemolysis Test – Direct Contact Method
        - Hemolysis Test – Extraction Method
        - Complement Activation (C3a & SC5b9)
        - Coagulation (PT & PTT)
    - Intracutaneous (Intradermal) Reactivity Test
    - USP Systemic Injection Test
    - Sensitization – Maximization Test
    - Material Mediated Rabbit Pyrogen Test
    - Bacterial Endotoxins (LAL) for Medical Devices

The Hi-Torque Winn is identical to the predicate device with respect to the materials, design, and manufacturing processes. Since no changes were made to the predicate device, no additional performance testing was conducted. The test results of the predicate device provide sufficient evidence to demonstrate the performance and safety of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL - 8 2010

Abbott Vascular
c\o Ms. Laarni Ricafort
Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K101648
Trade Name: Hi-Torque Winn Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 10, 2010
Received: June 10, 2010

Dear Ms. Ricafort:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K101648

Device Names: Hi-Torque Winn Guide Wire Family

Indications for Use: This Hi-Torque guide wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter_____ (Optional Format 1-1-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101648