K103101

FEB 10 2011

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 Inc.
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5. Contact Person	Kay Setzer
6. Date Prepared	September 22, 2010
7. Device Trade Name	HI-TORQUE BALANCE MIDDLEWEIGHT™ ELITE Guide Wire Family
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	BALANCE MIDDLEWEIGHT (BMW) Guide Wire (K971815, cleared July 9, 1997 and K973494, cleared December 12, 1997), HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II Guide Wire (K072460, cleared April 11, 2008), and the Terumo Runthrough (K063695, cleared April 4, 2007)

11. Device Description

The HI-TORQUE BALANCE MIDDLEWEIGHT™ ELITE Guide Wire is a steerable guide wire available in a maximum diameter of 0.0145" and in lengths of 190 cm and 300 cm. The distal segment of the guide wire is coated with hydrophilic coating to reduce friction for improved guide wire movement within the catheter. The distal tip is offered in a straight shapeable configuration and a pre-shaped "J" configuration. The proximal core has a maximum diameter of 0.0145". The proximal end of the guide wire is coated with hydrophobic coating, which reduces friction of the wire within a catheter. The ELITE Guide Wire is DOC® extendable in the 190 cm lengths. Over the coin DOC is a Wire Identifier to aid in distinguishing between two wires during use.

12. Indication for Use

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The guide wire may also be used with compatible stent devices during therapeutic procedures.

13. Technological Characteristics

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

14. Performance Data

In vitro bench testing, including catheter compatibility, tensile strength, torque strength, torqueability, coating adherence and integrity (particulate testing), and friction testing were conducted on the subject device. Biocompatibility testing included cytotoxicity, hemolysis (direct and indirect), acute systemic toxicity, complement activation, intracutaneous toxicity, acute systemic toxicity, sensitization, pyrogen, and in vivo thrombogenicity tests. The *in vitro* bench tests and the biocompatibility tests demonstrated that the HI-TORQUE BALANCE MIDDLEWEIGHT™ ELITE Guide Wire met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and therefore, the HI-TORQUE BALANCE MIDDLEWEIGHT™ ELITE Guide Wire Family may be considered substantially equivalent to the predicate devices.

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

Abbott Vascular, Inc
c/o Ms. Kay Setzer
Senior Regulatory Affairs Associates
26531 Ynez Road
Temecula, CA 92591

FEB 10 2011

Re: K103101
Trade/Device Name: HI-TORQUE Balance Middleweight™ Elite Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: January 25, 2011
Received: January 26, 2011

Dear Ms. Setzer:

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.

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 (240) 276-3150 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): K103101

Device Names: **HI-TORQUE BALANCE MIDDLEWEIGHT ELITE** Guide Wire Family

Indications for Use: This 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___ OR Over-The-Counter_____
(Per 21 CFR 801.109) (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 K103101