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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	P.O. Box 9018 26531 Ynez Road, Temecula, CA 92591
3. Telephone	(951) 914-3242
4. Fax	(951) 914-0339
5. Contact Person	Kay Setzer
6. Date Prepared	September 28, 2011
7. Device Trade Name	HI-TORQUE® POWERTURN Guide Wire Family
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	HI-TORQUE ADVANCE and ADVANCE LITE (K060449, cleared May 30, 2006), HI-TORQUE BALANCE MIDDLEWEIGHT ELITE (K103101, cleared Feb. 10, 2011), and Medtronic Vascular GTX Guide Wire, K091582, cleared Dec. 4, 2009)

11. Device Description

The HI-TORQUE POWERTURN Guide Wire Family has a diameter of 0.014" with a 190 cm extendable length and a 300 cm exchange length. The POWERTURN Guide Wire Family is available in three tip support models and is constructed from a 304V stainless steel core. Over the proximal coined section of the 190 cm model is a Wire Identifier consisting of a black PTFE shrink tube which is removable and is used to help physicians distinguish between two Abbott Vascular wires while being used simultaneously. The distal tip of the guide wire is available as a straight tip that is shapeable or as a pre-shaped "J". The straight shape allows the physician to shape the tip according to his/her preference and the pre-shaped tip provides the physician the convenience of a "J" shape without manual shaping.

12. Indication for Use

This HI-TORQUE guide wire is intended to facilitate the delivery of catheter-based interventional devices 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.

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(s) demonstrate that the technological characteristics such as product performance, design and indications for use are substantially equivalent to the current marketed predicate devices.

14. Performance Data

In vitro bench testing, including tip tensile strength, torque strength, torqueability, coating adherence and integrity (particulate testing), and friction testing were conducted on the new device. The *in vitro* bench tests demonstrated that the HI-TORQUE POWERTURN Guide Wire met all acceptance criteria and performed similarly to the predicate devices. It was not necessary to repeat biocompatibility testing as testing performed on the predicate device is applicable to the HI-TORQUE POWERTURN. No new safety or effectiveness issues were raised during the testing program and therefore, the
HI-TORQUE POWERTURN Guide Wire Family may be considered substantially equivalent to the predicate devices.

15. Conclusions

Test results from the *in vitro* bench testing conducted on the subject device demonstrate that the HI-TORQUE POWERTURN Guide Wire Family met all acceptance criteria and performed similarly to the predicate devices and that no new safety or effectiveness issues were raised during the testing program. Therefore, the HI-TORQUE POWERTURN 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

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Abbott Vascular
c/o Ms. Kay Setzer
Senior Regulatory Affairs Associate
26531 Ynez Road
Building G
Temecula, CA 92590

Re: K112957
Trade/Device Name: HI-TORQUE® POWERTURN Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 29, 2011
Received: October 4, 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): K112957

Device Names: HI-TORQUE POWERTURN Guide Wire Family

Indications for Use:

This HI-TORQUE guide wire is intended to facilitate the delivery of catheter-based interventional devices 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.

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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 K112957