January 12, 2018

Abbott Vascular
Aniket Khakhadiya
Regulatory Affairs Specialist
3200 Lakeside Drive
Santa Clara, California 95054

Re: K173795
Trade/Device Name: HI-TORQUE TurnTrac Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 12, 2017
Received: December 14, 2017

Dear Aniket Khakhadiya:

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.
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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)
K173795

Device Name
HI-TORQUE® TurnTrac Guide Wire Family

Indications for Use (Describe)
The HI-TORQUE TurnTrac Guide Wire Family is intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and /or reuse.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K173795 - 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  
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3. Telephone  
408-845-8314

4. Fax  
408-845-3689

5. Contact Person  
Aniket Khakhadiya

6. Date Prepared  
December 7, 2017

7. Device Trade Name  
HI-TORQUE® TurnTrac Guide Wire Family

8. Device Common Name  
Guide Wire

9. Device Classification Name  
Catheter Guide Wire (21 CFR 870.1330; Product Code - DQX)

10. Predicate Device Name  
HI-TORQUE VersaTurn Guide Wire Family (K141782, cleared on August 7, 2014)

11. Device Description

The HI-TORQUE (HT) TurnTrac Guide Wire Family includes steerable guide wires offered in several configurations by various support levels, tip loads, hydrophilic coating lengths, tip shape and guide wire lengths.

The HT TurnTrac Guide Wire Family will be available with the features as listed below:

- 2 tip loads: 0.6g and 0.9g
- 2 support levels: *HT TurnTrac Moderate Support (MS) and HT TurnTrac Extra Support (ES)*
- 2 coating lengths: *Fully Coated (HC), Uncoated Tip (pHC)*
- 1 tip shape: *Straight*
- 2 lengths: 190 cm, 300cm

The HI-TORQUE TurnTrac Guide Wire Family has a maximum diameter of 0.0142” or 0.0145” depending on the support level and is compatible with devices designed for use with 0.014” guide wires. The HI-TORQUE TurnTrac Guide Wire Family includes a shaping tool, which is clipped on to the outer packaging coil after the final assembled
product has been inserted into the packaging coil. This accessory is to aid the physician in shaping the distal portion of the guide wire, if desired.

12. **Indication for Use**

The HI-TORQUE TurnTrac Guide Wire Family is intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA). This guide wire may also be used with compatible stent devices during therapeutic procedures.

This device is designed and intended for **ONE-TIME USE ONLY.** Do not resterilize and / or reuse.

13. **Technological Characteristics**

Comparison of the subject device and predicate device demonstrates that the technological characteristics such as product performance, functional specification, operating principle, design and materials (with minor modifications), and indications for use are substantially equivalent to the currently marketed predicate device.

14. **Performance Data**

*In vitro* bench testing, including tip tensile strength, torsional wire strength, torqueability, integrity (particulate testing), and friction testing were conducted on the modified device. The results from the *in vitro* bench tests demonstrated that the HI-TORQUE TurnTrac Guide Wire met all acceptance criteria and performed similarly to the predicate device. The results obtained from the biocompatibility testing indicate that the HI-TORQUE TurnTrac Guide Wire Family may be considered substantially equivalent to the predicate device.

15. **Conclusions**

Test results from the *in vitro* bench testing conducted on the subject device demonstrate that the HI-TORQUE TurnTrac Guide Wire met all acceptance criteria and performed similarly to the predicate device. Therefore, the HI-TORQUE TurnTrac Guide Wire Family may be considered substantially equivalent to the predicate device.