July 30, 2020

Abbott Vascular
Charlotte Pullman
Specialist, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95094

Re: K201834
Trade/Device Name: HI-TORQUE PROCEED Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 30, 2020
Received: July 2, 2020

Dear Charlotte Pullman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Lydia Glaw, PhD.
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201834

Device Name
HI-TORQUE PROCEED GUIDE WIRE

Indications for Use *(Describe)*
This guide wire is intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal angioplasty (PTA) in arteries such as the femoral, popliteal, and infrapopliteal arteries. This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may 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 (K201834)

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 **(with Business Trade Name as Abbott Medical)**
2. Submitter's Address	3200 Lakeside Dr., Santa Clara, CA 95054
3. Telephone	408-845-0652
4. Fax	408-845-3333
5. Contact Person	Charlotte Pullman
6. Date Prepared	June 30, 2020
7. Device Trade Name	HI-TORQUE PROCEED Guide Wire
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (21 CFR 870.1330; Product Code - DQX)
10. Predicate Device Name	HT InfilTrac (K193126, cleared on December 11, 2019)

11. Device Description

The HI-TORQUE (HT) Proceed Guide Wire Family includes steerable guide wires offered in several tip load and guide wire length configurations.

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

- 2 tip loads: 11g and 14g
- 1 coating length: *Uncoated Tip*
- 1 tip shape: *Pre-shaped, micro-J*
- 2 lengths: *190 cm, 300cm*

The HT Proceed Guide Wires are designed to be compatible with devices designed for use with 0.014" guide wires. The HT Proceed Guide Wire Family has a maximum diameter of 0.0144". The distal tip has a radiopaque length of 3.0 cm.

12. Indication for Use

This guide wire is intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal angioplasty (PTA) in arteries such as the femoral, popliteal, and infra-popliteal arteries. This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may 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 and Substantial Equivalence

The HT Proceed Guide Wire family (subject device) is technologically identical to the predicate device; both the subject and predicate devices use identical functional specifications, operating principle, materials, and design, and have an identical sterilization method, shelf life, and packaging components-materials.

The difference between the HT Proceed Guide Wire and its predicate device is the indication for use; the indication for use of the subject device is a subset of the indication for use of the originally cleared predicate device (HT InfilTrac, K193126, cleared December 11, 2019) and is not expanded outside of the currently cleared indication for the predicate device.

A comparison between the subject device and its predicate was performed to support a substantial equivalence determination. The substantial equivalence comparison included the device's indications for use, design, technological characteristics, materials, operating principle, sterilization, shelf life and packaging. The conclusion of the comparison analysis is that the subject device is substantially equivalent to the currently marketed predicate device.

14. Performance Data

The subject device is identical to the predicate device, HT InfilTrac, therefore *in vitro* bench testing and simulated use testing were leveraged from the predicate device to demonstrate that HT Proceed meets all acceptance criteria requirements as specified in the product specification and external guidance documents.

Results of these tests demonstrated that the HT InfilTrac Guide Wire Family (and, therefore, the HT Proceed Guide Wire) met the functional, dimensional and simulated use testing acceptance criteria requirements as specified in the product specification and external guidance documents. Based on the results, Abbott Vascular considers that the HT Proceed Guide Wire Family is substantially equivalent to the predicate device- HT InfilTrac Guide Wire.

15. Conclusions

The subject device is technologically identical to the predicate device, HT InfilTrac, and therefore test results from the performance testing conducted on the predicate device (HT InfilTrac, K193126) can be leveraged. The results demonstrated that the HT Proceed Guide Wire Family met all acceptance criteria requirements. Thus, Abbott Vascular considers the subject device – the Hi-Torque Proceed Guide Wire Family – to be substantially equivalent to the currently marketed predicate device - the HT InfilTrac Guide Wire.