April 8, 2020

Abbott Vascular
Shilpa Satishchandra
Project Manager, Regulatory Affairs
3200 Lakeside Drive
Santa Clara, California 95054

Re: K200144
Trade/Device Name: HI-TORQUE Steelcore Bare Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 10, 2020
Received: February 11, 2020

Dear Shilpa Satishchandra:

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
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)*

K200144

Device Name
HI-TORQUE Steelcore™ Bare Guide Wire

Indications for Use *(Describe)*

The Hi-Torque Steelcore™ Bare Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. It is not intended for use in the cerebral 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.

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

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SECTION 5
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 **(with Business Trade Name as Abbott Medical)**
2.	Submitter's Address	3200 Lakeside Dr., Santa Clara, CA 95054
3.	Telephone	408-845-0775
4.	Fax	408-845-3743
5.	Contact Person	Shilpa Satishchandra
6.	Date Prepared	April 03, 2020
7.	Device Trade Name	HI-TORQUE Steelcore™ Bare 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 Steelcore™ 18 Guide Wire (K982876, cleared on August 14, 1998)
11.	Reference Devices	HT Command®18 Guide Wire (K172073 cleared on cleared on August 25, 2017) HT InfilTrac™ Guide Wire Family (K193126, cleared on December 11, 2019) HT Steelcore 18 LT Guidewire (K982876)

12. Device Description

The HT Steelcore Bare Guide Wire is classified under the product code DQX, with the regulation number 21 CFR 870.1330, Catheter guide wire. The HT Steelcore Bare Guide Wire is a steerable wire offered in only one configuration and is designed to be used with devices compatible with 0.018" guide wires.

The HT Steelcore Bare Guide Wire is developed with 300 cm length and has a maximum diameter of 0.019". The distal tip has a radiopaque length of 5.0 cm. The HT Steelcore Bare Guide Wire will be available with the features as listed below:

- Proximal Coating - Single Coat Silicone Based hydrophobic coating.
- Distal Coating - Dual Coat Silicone Based Hydrophobic Coating.

13. Indication for Use

Hi-Torque Steelcore Bare Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. It is not intended for use in the cerebral vasculature.

14. Technological Characteristics and Substantial Equivalence

The HT Steelcore Bare Guide Wire has the same Indications for Use and has similar technological characteristic to the predicate device – HT Steelcore 18 Guide Wire. They use the same functional specifications, operating principle, materials and design (with minor modifications). They have the same, shelf life and packaging components-materials and meet the same Sterility Assurance Levels(SAL) of 10^{-6}.

Table 14-1 illustrates comparison between the subject device - HT Steelcore Bare Guide Wire and its predicate. This comparison 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 - HT Steelcore Bare Guide Wire is substantially equivalent to the currently marketed predicate device - HT Steelcore 18 Guide Wire.

Table 14-1 Comparison between HT Steelcore Bare guidewire and HT Steelcore 18 guidewire

Attribute	Subject Device HT Steelcore Bare Guide Wire	Predicate Device HT Steelcore 18 Guide Wire (K982876)
Device Classification	Class II 74DQX CFR § 870.1330	Class II 74DQX CFR § 870.1330
Classification Name	Catheter Guide Wire	Catheter Guide Wire

Attribute	Subject Device HT Steelcore Bare Guide Wire	Predicate Device HT Steelcore 18 Guide Wire (K982876)
Overall Design	Core to Tip 0.018” Wire	Core to Tip 0.018” Wire
Tip Design	Flattened Tip	Flattened Tip
Tip Shape	Straight (shapeable)	Straight (shapeable)
Distal Coating	Silicone Based Hydrophobic Coating	Silicone Based Hydrophobic Coating
Proximal Coating	Silicone Based Hydrophobic Coating	PTFE
Diameter	0.0190” max. (0.48mm)	0.0190” max. (0.48mm)
Length	300cm	130, 190, 300cm
Radiopaque Tip	Yes	Yes
Indications for Use	The HI-TORQUE STEELCORE™ BARE Guide Wire is intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures. It is not intended for use in the cerebral vasculature.	All Hi-Torque Guide Wires are intended to facilitate the placement and exchange of diagnostic and therapeutic devices during intravascular procedures.
Sterilization	E-beam radiation	EtO and E-Beam
Shelf Life	2 years	2 years
Conditions of use	Single-use device for procedure performed in a catheterization laboratory or surgical suite	Single-use device for procedure performed in a catheterization laboratory or surgical suite
Preparation for Use	Flush hoop dispenser and shape guide wire tip as necessary	Flush hoop dispenser and shape guide wire tip as necessary

15. Performance Data

Performance testing was conducted in accordance with the FDA guidance: *Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling: 2019*, and pertinent standards as recommended by the FDA guidance document as applicable. Testing conducted included:

- Biocompatibility
- Sterilization
- Pyrogen Validation

- Shelf life and Packaging
- Non-clinical bench testing

The performance testing passed with results meeting acceptance criteria, and demonstrated that the HT SteelCore Bare Guide Wire is as safe and as effective, compared to the predicate device, in performing its intended use.

16. Conclusions

Test results from the performance testing conducted demonstrates that the HT Steelcore Bare Guide Wire met all acceptance criteria requirements. Therefore, Abbott Vascular considers the subject device - HI-TORQUE Steelcore Bare Guide Wire to be as safe and effective as the currently marketed predicate device - HT Steelcore 18 Guide Wire for its intended use.