July 25, 2025

Abbott Medical
Irina Ignatenko
Senior Regulatory Affairs Specialist
3200 Lakeside Drive
Santa Clara, California 95054

Re: K250552
Trade/Device Name: Hi-Torque Command 14 ST Guide Wire and Hi-Torque Command 14 MT Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 25, 2025
Received: June 27, 2025

Dear Irina Ignatenko:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

LYDIA S. GLAW -S

Digitally signed by LYDIA S. GLAW -S
Date: 2025.07.25 16:52:31 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250552

Device Name
Hi-Torque Command 14 ST Guide Wire, Hi-Torque Command 14 MT Guide Wire

Indications for Use *(Describe)*
The Hi-Torque Command™ 14 ST Guide Wire and Hi-Torque Command™ 14 MT Guide Wire are indicated to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. The guide wires may also be used with compatible stent devices during therapeutic procedures.
The guide wires 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.

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.

510(k) Summary
Per 21 CFR §807.92

510(k) Number	K250552
Date Prepared	February 25, 2025
Submitter Name & Address	Abbott Medical 3200 Lakeside Drive Santa Clara, CA 95054
Contact Person	Irina Ignatenko Phone: (774) 613-1131
Proprietary / Trade Name	Hi-Torque Command™ 14 ST Guide Wire and Hi-Torque Command™ 14 MT Guide Wire
Common / Usual Name	Wire, Guide, Catheter
Product Classification	Class II
Product Code	DQX
Product Regulation Number	21 CFR 870.1330
Predicate Device	K240997: Hi-Torque Command™ 14 ST Guide Wire and Hi-Torque Command™ 14 MT Guide Wire
Device Description	The Hi-Torque Command™ 14 ST Guide Wire (guide wire with short taper) and Hi-Torque Command™ 14 MT Guide Wire (guide wire with medium taper) have a maximum diameter of 0.0144" (0.366 mm) and are provided in 210 cm and 300 cm lengths. The distal tip of the guide wire is available as a straight tip or an angled tip, both of which are shapeable.
Indications for Use	The Hi-Torque Command™ 14 ST Guide Wire and Hi-Torque Command™ 14 MT Guide Wire are indicated to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. The guide wires may also be used with compatible stent devices during therapeutic procedures. The guide wires 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.
Comparison of Subject to Predicate Device	The intended use and indications for use for the subject device is identical to the predicate device. Device design, materials composition, and technological characteristics are identical between the subject and predicate devices.

Summary of Non-Clinical Testing	The following verification and validation testing were completed to support the labeling changes in scope of this 510(k) submission. Data support the conclusion that the labeling updates do not negatively impact the safe and effective use of the subject device; and that the subject and predicate devices are substantially equivalent. • Friction • Kink resistance • Bending durability • Fracture • Torsional wire strength • Tip tensile strength • Particulates • Rotational accuracy • Coating integrity • Simulated use
Summary of Clinical Testing	Clinical studies were not needed to support substantial equivalence between subject and predicate devices.
Statement of Equivalence	The subject and predicate devices have the identical intended use, indications for use, device design, material composition, and technological characteristics. Testing data to evaluate the labeling changes in scope of the 510(k) submission demonstrate that the subject and predicate devices are substantially equivalent in safety and effectiveness.