



November 6, 2024

Abbott Medical
Angeline Chooi
Principal Regulatory Affairs Specialist
3200 Lakeside Drive
Santa Clara, California 95054

Re: K240997

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: October 7, 2024
Received: October 7, 2024

Dear Angeline Chooi:

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: 2024.11.06
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Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K240997

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 intended 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.

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510(k) Summary
Per 21 CFR §807.92

510(k) Number	K240997
Date Prepared	April 9, 2024
Submitter Name & Address	Abbott Medical 3200 Lakeside Drive Santa Clara, CA 95054
Contact Person	Angeline Chooi 408-845-0652
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	Hi-Torque Command Guide Wire Family (K122573) The following reference device is used in this submission: Hi-Torque Proceed Guide Wire Family (K201834)
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 Indications for Use for the subject device, Hi-Torque Command 14 ST Guide Wire and Hi-Torque Command 14 MT Guide Wires, is identical to the predicate device, Hi-Torque Command Guide Wire Family. They have similar functional specifications, materials and design (with minor differences).

Summary of Non-Clinical Testing	The Hi-Torque Command™ 14 ST and Hi-Torque Command™ 14 MT Guide Wires were evaluated through performance testing which included non-clinical bench testing and simulated use testing. The test results demonstrate the Hi-Torque Command™ 14 ST and Hi-Torque Command™ 14 MT Guide Wires meets functional, dimensional, and simulated use testing acceptance criteria. The following biocompatibility tests were conducted per ISO 10993 series of standards for an external communicating device with limited contact with circulating blood: • Cytotoxicity; • Sensitization; • Irritation/intracutaneous reactivity; • Acute systemic toxicity; • Material-mediated pyrogenicity; • Complement activation (SC5b-9 pathway); • ASTM Partial Thromboplastin Time and Platelet & Leukocyte Count Assay; and • Direct and indirect hemolysis The following verification and validation testing were completed: • Tip Appearance • Polyurethane Covering Appearance • Proximal Coatings • Polyurethane Covering Length (Coating Length) • Overall Length • Outside Diameter • Surface Appearance • Pre-Shaped Tip Appearance • Distal Solder Length • Proximal Solder Length • Distal Tip Coil Length (radiopaque tip length) • Distal Tip Grind Outer Diameter • Tip Tensile Strength • Torsional Wire Strength (Torque Strength) • Dissimilar Metal Weld Strength • Rotary Bend Strength • Friction Test (Lubricity) • GW Particulates • Kink Resistance • Tip Load (Tip Flexibility) • Rotational Accuracy (Torqueability Test)
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	• Particulates ($\geq 70 \mu\text{m}$) • Large Particulates ($\geq 200 \mu\text{m}$ and $\geq 300 \mu\text{m}$) • Corrosion Resistance • Coating Integrity • Bending Durability (Flexing) • Fracture • Simulated Use
Summary of Clinical Testing	Clinical studies were not needed to support substantial equivalence between subject and predicate devices.
Statement of Equivalence	The Indications for Use for the subject device, Hi-Torque Command 14 ST Guide Wire and Hi-Torque Command 14 MT Guide Wires, is identical to the predicate device, Hi-Torque Command Guide Wire Family. Subject and predicate devices have similar specifications, materials and design. The results demonstrated that the Hi-Torque Command 14 ST Guide Wire and Hi-Torque Command 14 MT Guide Wires met all acceptance criteria. Non-clinical testing has been completed to demonstrate substantial equivalence between subject and predicate devices.