November 26, 2019

Heraeus Medical Components, LLC
Chelsea Pioske
Regulatory Affairs Manager
2605 Fernbrook Lane North, Suite J
Plymouth, Minnesota 55447

Re: K191502
Trade/Device Name: Heraeus Peripheral Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 25, 2019
Received: October 28, 2019

Dear Chelsea Pioske:

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)*
K191502

Device Name
Heraeus Peripheral Guidewire

Indications for Use *(Describe)*
Intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in peripheral arteries including but not limited to femoral, popliteal, and infra-popliteal arteries. This guide wire may also be used with compatible interventional devices during therapeutic procedures. The guide wire 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.

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

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510(k) Summary K191502

Submitter:	Heraeus Medical Components, LLC 1805 Fernbrook Lane North, Suite J Plymouth, MN 55447 USA
Contact Person:	Chelsea Becker, Regulatory Manager 1805 Fernbrook Lane North, Suite J Plymouth, MN 55447 USA 763-225-6500 (voice) 763-559-7676 (fax)
Date Prepared:	November 25th, 2019
Trade Name:	Heraeus Peripheral Guidewire
Common Name:	Guidewire
Classification:	Class II Regulation Number: 21 CFR 870.1330 Catheter guide wire
Product Code:	DQX
Predicate Device:	The subject device is substantially equivalent to K122573; Abbott Hi-Torque Command guidewire.
Device Description:	The Heraeus Peripheral Guidewire is a guidewire constructed using a steel core with an optional nitinol alloy tip encapsulated by polymer and lubricious outer layer. The distal polymer includes a radiopaque loading, and the distal polymer section has a hydrophilic coating.
Indication for Use:	The peripheral guidewire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in peripheral arteries including but not limited to femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible interventional devices during therapeutic procedures. The guide wire 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.
Contraindications:	Not intended for use in the coronary or cerebral vasculature.

Principle of Operation:

The Heraeus Peripheral Guidewire is manually inserted into vasculature through a compatible guiding catheter and advanced to the target region.

Substantial Equivalence Comparison:

The Heraeus Peripheral Guidewire is substantially equivalent to the Abbott Hi-Torque Command guidewire (K122573). Substantial equivalence is based on indications for use, physical and technological characteristics, and comparative device testing.

Indications for use:

- The indications for use for the Heraeus Peripheral Guidewire are equivalent to the predicate.

Fundamental scientific technology

- Dimensional characteristics – the length and diameter of the device are similar to the dimensions of the predicate devices
- Materials – the device is constructed of equivalent materials to provide equivalent performance characteristics and coating properties
- Operating principle - equivalent to the predicate device
- Packaging materials - equivalent to the predicate device
- Sterility assurance level and method of sterilization - equivalent to the predicate devices

Performance Testing:

In vitro bench tests were utilized to demonstrate equivalence with reference to FDA Guidance - Coronary and Cerebrovascular Guidewire Guidance - January 1995.
The performance testing assessment supports that the biocompatibility, shelf life, and functional specifications of the proposed guidewire device were met.

The Heraeus Peripheral Guidewire device test data supports the claims of substantial equivalence to the predicate devices. Biological Safety of the predicate device has been established through biocompatibility testing carried out in compliance with ISO 10993-1:2018 and the 2016 FDA guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

The following bench tests were conducted or evaluated to support the proposed device:

- Biocompatibility testing:

    - Cytotoxicity
    - Sensitization
    - Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Pyrogenicity Testing
    - Hemolysis
    - In-Vivo Thrombogenicity
    - Coagulation
    - Platelet Activation
    - Haematology
    - Complement Activation
- Corrosion resistance
- Dimensional inspection
- Sterile package integrity testing
- Tensile strength
- Tip flexibility
- Torque strength
- Torqueability
- Kink/Fracture Resistance
- Kink resistance
- Radiopacity
- Coating Integrity, Lubricity
- Track/Simulated Use
- Particulate Evaluation

Conclusion:

The Heraeus Peripheral Guidewire met all predetermined acceptance criteria and compared favorably with the predicate

Heraeus considers the Heraeus Peripheral Guidewire to be equivalent to the predicate device. This conclusion is based upon the fact that the device has an equivalent intended use, and there are no differences that raise new types of questions of safety and effectiveness.