DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 20, 2017

Heraeus Medical Components, LLC
Margaret Batchelder
Principal Regulatory Specialist
2605 Fernbrook Lane North, Suite J
Plymouth, Minnesota 55447

Re: K173052
Trade/Device Name: Heraeus TMW Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 27, 2017
Received: September 28, 2017

Dear Margaret Batchelder:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K173052

Device Name
Heraeus TMW Guidewire

Indications for Use *(Describe)*
The Heraeus TMW Guidewire is intended to facilitate the introduction and placement of catheters and interventional devices during Percutaneous Transluminal Angioplasty (PTA) and/or Percutaneous Transluminal Coronary Angioplasty (PTCA).

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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6 510(k) Summary -- K173052

Submitter:	Heraeus Medical Components, LLC 1805 Fernbrook Lane North, Suite J Plymouth, MN 55447
Contact Person:	Margaret Batchelder, Principal Regulatory Specialist 1805 Fernbrook Lane North, Suite J Plymouth, MN 55447 763-225-6675 (voice) 763-559-7676 (fax)
Summary Preparation Date	September 27, 2017
Device Name	Heraeus TMW Guidewire
Device Classification:	Common Name: Guidewire Classification Name: Catheter, Guidewire Device Classification: Class II, 21 CFR §870.1330 Product Code: DQX
Intended Use:	The Heraeus TMW Guidewire is intended to facilitate the introduction and placement of catheters and interventional devices during Percutaneous Transluminal Angioplasty (PTA) and/or Percutaneous Transluminal Coronary Angioplasty (PTCA).
Contraindications:	The guidewire is not intended for use in the cerebral vasculature.
Device Description	Heraeus TMW Guidewire is a steerable guidewire constructed of a bi-metal core wire. The distal core is made of Triton™ Nitinol alloy and has a coiled wire feature at the distal end. The proximal core is comprised of PTFE coated Stainless Steel material. The wire is available in .014" diameter and lengths ranging from 180 to 300 cm. The distal segment is coated with hydrophilic coating and is shapeable with a 3 cm radiopaque distal tip.
Predicate Device:	The subject device is substantially equivalent to the Hi-Torque Balance Middleweight Guidewire (K152709, 10/21/2015) manufactured by Abbott Vascular.
Principle of Operation:	The Heraeus TMW Guidewire is operated by a manual process.

Comparison of Technological Characteristics	The key technological and performance similarities examined between the approved devices and the proposed Heraeus TMW Guidewire device are as follows: Indications for use - The Indications for use for the proposed device is a subset of indications for use of the predicate device as proposed device, Fundamental scientific technology, including design are equivalent to the predicate devices Operating principle - equivalent to the predicate devices Packaging materials - equivalent to the predicate device Sterility assurance level and method of sterilization - equivalent to the predicate devices The length and diameter of the device are equivalent to the dimensions of the predicate devices. The proposed device and that of the predicate device are identical in that they are constructed with equivalent materials to provide equivalent tip stiffness, torque responses, and coating properties. The proposed device has equivalent tip stiffness characteristics to that the predicate device
Substantial Equivalence	The Heraeus TMW Guidewire System is substantially equivalent to the substantially equivalent to the Hi-Torque Balance Middleweight Guidewire (K152709). Substantial equivalence, which is summarized in the following table, is based on indications for use, physical and technological characteristics, and comparative device testing.

	TMW Guidewire (current submission)	Abbott Vascular Hi-Torque Balance Middleweight Universal II Guidewire (K152709)	Abbott Vascular Hi-Torque Balance Middleweight Elite Guidewire (K152709)
Device Common/Usual Name	Catheter Guide Wire	Catheter Guide Wire	Catheter Guide Wire
Device Class	Class II	Class II	Class II
Product Code / Regulation	DQX / 21 CFR 870.1330	DQX / 21 CFR 870.1330	DQX / 21 CFR 870.1330
Regulation Name	Catheter Guide Wire	Catheter Guide Wire	Catheter Guide Wire
Prescription Use	Rx Only	Rx Only	Rx Only
Indications for Use	The Heraeus TMW Guidewire is intended to facilitate the introduction and placement of catheters and interventional devices during Percutaneous Transluminal Angioplasty (PTA) and/or Percutaneous Transluminal Coronary Angioplasty (PTCA).	To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.	To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may also be used with compatible stent devices during therapeutic procedures.
Guidewire OD	0.014”	0.014”	0.014”
Guidewire Length	180 & 300 cm	190 & 300 cm	190 & 300 cm
Guidewire Materials	Nitinol Cobalt, Stainless Steel, Pebax, Platinum Tungsten, Solder, and Adhesive	Nitinol, Stainless Steel, Radiopaque Coil, Solder, Polymer Jacket, Adhesive	Nitinol, Stainless Steel, Radiopaque Coil, Solder, Adhesive
Guidewire Coating	PTFE, Hydrophilic coating	PTFE, Hydrophilic coating	PTFE, Hydrophilic coating
Tip Shape	Straight Tip	Straight, J-Tip	Straight, J-Tip
Sterile Device?	Yes	Yes	Yes
Sterilization Type	Ethylene Oxide	Irradiation	Irradiation
EO Sterilization Residuals	Per ISO 10993-7	N/A	N/A
Disposable / Reusable	Disposable	Disposable	Disposable

Performance Testing: In vitro bench tests were utilized to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995".

The performance testing assessment supports that the biocompatibility, shelf life, and functional specifications of the proposed Guidewire device were met.

The Heraeus TMW 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 ISO10993-1:2009 and G95-1, FDA General Program Memorandum: Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

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

- biocompatibility testing (including: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogen Testing, Hemolysis, Complement Activation, In-Vivo Thrombogenicity)
- particulate testing
- corrosion resistance
- dimensional inspection
- sterilization
- sterile package integrity testing
- tensile strength
- tip stiffness
- torque response
- corrosion resistance
- radiopacity
- tip stiffness

The Heraeus TMW Guidewire System met all predetermined acceptance criteria and compared favorably with the predicate device.

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