November 9, 2017

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

Re: K170664
Trade/Device Name: Odyssey Micro Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 11, 2017
Received: October 12, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170664

Device Name
Odyssey Micro Catheter

Indications for Use *(Describe)*

The Odyssey Micro Catheter is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another. The Odyssey Micro Catheter is also intended to assist in the infusion of contrast media. The micro catheter is not intended to be used in the neurovasculature.

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 K170664

Submitter:	Heraeus Medical Components, LLC 2605 Fernbrook Lane North, Suite J Plymouth, MN 55447 USA
Contact Person:	Margaret Batchelder, Principal Regulatory Specialist 2605 Fernbrook Lane North, Suite J Plymouth, MN 55447 USA 763-225-6675 (voice) 763-559-7676 (fax)
Date Prepared:	October 25, 2017
Trade Name:	Odyssey Micro Catheter
Classification:	Class II Regulation Number: 21 CFR 870.1250 Percutaneous Catheter
Product Code:	DQY
Predicate Device:	The subject device is substantially equivalent to K151103; ASAHI Corsair Microcatheter manufactured by Asahi Intecc Co., LTD.
Device Description:	The Odyssey Micro Catheter is a single lumen catheter constructed using a PTFE liner inside of metallic coil and a polymer outer layer. The distal tip is a radiopaque polymer material and the distal 30 cm to 60 cm of the micro catheter has a hydrophilic coating. The key components of the catheter are the core, coil(s), tip, and coatings.
Indication for Use:	The Odyssey Micro Catheter is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another. The Odyssey Micro Catheter is also intended to assist in the infusion of contrast media. This micro catheter is not intended to be used in the neurovasculature.
Contraindications:	None known.

Principle of Operation:

The Odyssey Micro Catheter is manually inserted into vasculature through a compatible guiding catheter over a compatible guidewire and advance with the guidewire to the target region.

Comparison of Technological Characteristics:

The key technological and performance similarities examined between the approved devices and the proposed 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 similar to the dimensions of the predicate devices.

The proposed device and that of the predicate device are equivalent in that they are constructed with equivalent materials to provide equivalent performance characteristics and coating properties.

Substantial Equivalence:

The Heraeus Odyssey Micro Catheter is substantially equivalent to the ASAHI Corsair Microcatheter (K151103). Substantial equivalence, which is summarized in the following table, is based on indications for use, physical and technological characteristics, and comparative device testing.

	Odyssey Micro Catheter	**Predicate: Asahi Corsair Microcatheter (**K151103)
Device Common/Usual Name	Catheter, Percutaneous	Catheter, Percutaneous
Device Class	Class II	Class II
Product Code / Regulation	DQY / 21 CFR 870.1250	DQY / 21 CFR 870.1250
Regulation Name	Percutaneous catheter	Percutaneous catheter

	Odyssey Micro Catheter	Predicate: Asahi Corsair Microcatheter (K151103)
Indications for Use	The Odyssey Micro Catheter is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another. The Odyssey Micro Catheter is also intended to assist in the infusion of contrast media. This micro catheter is not intended to be used in the neurovasculature.	The ASAHI Corsair Microcatheter is intended to provide support to facilitate the placement of Guide wires in the coronary and peripheral vasculatures and can be used to exchange one guide wire for another. The Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral, and abdominal vasculatures.
Catheter OD	0.032 in. / 0.042 in.	0.037 in.
Catheter Length	90 - 225 cm	90 - 150 cm
Catheter Materials	Stainless Steel, Pebax, Pellethane, PTFE, Adhesive, SBC, Polycarbonate	Stainless Steel, Tungsten, Polymer Jacket, PTFE, Adhesive, SBC, Polycarbonate
Catheter Coating	Hydrophilic coating	Hydrophilic coating
Sterile Device	Yes	Yes
Sterilization Type	Ethylene Oxide	Ethylene Oxide
Disposable / Reusable	Disposable	Disposable

Performance Testing:

In vitro bench tests were utilized to demonstrate equivalence with reference to ISO 10555-1:2013, Intravascular catheters – sterile and single-use catheters – Part 1: General requirements.

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

The Odyssey Micro Catheter 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:
    - Cytotoxicity
    - Sensitization
    - Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Pyrogenicity Testing
    - Hemolysis
    - Complement Activation
    - In-Vivo Thrombogenicity
    - Chemical Characterization
- Particulate testing
- Corrosion resistance
- Dimensional inspection
- Sterile package integrity testing
- Tensile strength
- Torque strength
- Kink resistance
- Radiopacity
- Flow rate
- Burst pressure/freedom from leakage

The Odyssey Micro Catheter met all predetermined acceptance criteria and compared favorably with the predicate device.

Conclusion: Heraeus considers the Odyssey Micro Catheter 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.