August 15, 2022

Merit Medical Systems, Inc.
Susan Christensen
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K213845
Trade/Device Name: HeRO Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: July 12, 2022
Received: July 14, 2022

Dear Susan Christensen:

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 Carmen Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213845

Device Name
HeRO Graft

Indications for Use *(Describe)*
The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the KDOQI guidelines as patients who:

• Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts).
• Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography.
• Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography (e.g. fistula/graft salvage).
• Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography.
• Have a compromised central venous system or central venous stenosis (CVS) as determined by a history of previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling) or venography.
• Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4.

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: K213845

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4789 (801) 208-3365 Susan Christensen August 15, 2022 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	HeRO® Graft Vascular Graft Prosthesis Prosthesis, Vascular Graft, of 6mm and Greater Diameter II DSY 870.3450 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: This predicate has not been subject to a design-related recall	HeRO Graft Prosthesis, Vascular Graft, of 6mm and Greater Diameter K203724 Merit Medical Systems, Inc.
Reference Device	No reference devices were used in this submission.	
Device Description	The HeRO Graft is a non-autogenous (i.e., synthetic) vascular graft prosthesis which provides arterial venous access with continuous outflow into the central venous system. The HeRO Graft is composed of the following components: (1) Venous Outflow Component (VOC) with delivery stylet, (2) Arterial Graft Component (AGC) or HeRO Adapter with Support Seal (used in conjunction with commercial vascular grafts), and (3) Accessory Component Kit (ACK). The VOC consists of a radiopaque silicone base tube, a nitinol braid (imparts kink and crush resistance), a distal radiopaque marker band, and an outer silicone elastomer encapsulation layer. During surgery, the VOC is cut to length for the patient anatomy and then advanced over the barbs of the AGC Connector or HeRO Adapter. The AGC is a conventional ePTFE vascular graft with a guideline and beading near the custom titanium alloy connector to provide kink resistance. As an alternative to the AGC, the titanium alloy HeRO Adapter with Support Seal allow the clinician to choose one of the commercially available 6mm ID vascular grafts qualified for use with the HeRO Graft. The HeRO Graft Accessory Component Kit is intended to aid in the implantation of the HeRO Graft and contains instruments including, introducers, dilators, hemostasis valve with stopcock, disposable clamp, and hemostasis plug. The HeRO Graft is a fully subcutaneous surgical implant single-use device provided sterile via ethylene oxide for long-term (>30 day) use.	

Indications for Use	The HeRO Graft is indicated for end stage renal disease patients on hemodialysis who have exhausted all other access options. These catheter-dependent patients are readily identified using the KDOQI guidelines as patients who: • Have become catheter-dependent or who are approaching catheter-dependency (i.e., have exhausted all other access options, such as arteriovenous fistulas and grafts). • Are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or venography. • Are failing fistulas or grafts due to poor venous outflow as determined by access failure or venography (e.g. fistula/graft salvage). • Have poor remaining venous access sites for creation of a fistula or graft as determined by ultrasound or venography. • Have a compromised central venous system or central venous stenosis (CVS) as determined by a history of previous access failures, symptomatic CVS (i.e., via arm, neck, or face swelling) or venography. • Are receiving inadequate dialysis clearance (i.e., low Kt/V) via catheters. KDOQI guidelines recommend a minimum Kt/V of 1.4. There is no change in the Indications for Use Statement from the predicate to the subject device.
Comparison to Predicate Device	The subject HeRO Graft device and Accessory Component Kit are similar in design and technological characteristics to the predicate HeRO Graft and Accessory Component Kit. The comparison between the subject device and predicate devices is based on the following: • Same Clinical use • Same Indications for use • Same Basic Design • Same fundamental technology/principle of operation • Same sterilization methods • Same intended use The following technological differences exist between the subject device and predicate device: • Labeling • Packaging Configuration • Different material types that meet ISO 10993-1 (ACK Components) • Minor dimensional differences (ACK Components) The labeling, packaging, material and dimensional differences are considered technological differences but do not raise different questions of safety and effectiveness and can be evaluated with performance testing.

Performance Data	FDA guidance documents and recognized performance standards have been established for Vascular Prostheses under Section 514 of the Food, Drug and Cosmetic Act. A battery of tests was performed based upon the risk analysis and the requirements of the following internationally recognized standards and guidance documents pertaining to the device performance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed HeRO Graft including Accessory Component Kit meets the acceptance criteria established by the standards as they apply to device safety and efficacy. • FDA guidance document: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" • ISO 11607-1, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems • ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems • ISO 2233-2000, Packaging – Complete, Filled Transport Packages and Unit Loads – Conditioning for Testing • ASTM F1929-15 – Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration • ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) • ASTM F88-15 Standard Test Method for Seal Strength of Flexible Barrier Materials • ASTM F1140/F1140M-13, Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages • ISO 11135, Sterilization of health-care products – ethylene oxide – requirements for the development, validation and routine control of a sterilization process for medical devices • ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process • ISO 10993-4, Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood • ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals • ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type hypersensitivity • ISO 10993-11, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity • ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials • USP 43-NF38:2020, <151> Pyrogen Test (USP Rabbit Test) • ISO 11070, Sterile single-use intravascular introducers, dilators, and guidewires • ISO 594-2, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock Fittings

	The following performance data were provided in support of the substantial equivalence determination. Biocompatibility Testing The biocompatibility evaluation for the HeRO Graft Accessory Component Kit was conducted in accordance with the FDA guidance document: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Hemolysis • Thrombogenicity • Complement Activation The HeRO Graft Accessory Component Kit met the biocompatibility requirements for externally communicating device with circulating blood contact for a limited (< 24 hours) duration. The results of the following performance tests demonstrated that the subject HeRO Graft Accessory Component Kit met the acceptance criteria applicable to the safety and efficacy of the device.
Performance Data (Continued)	Performance / Design Validation Testing: • Dimensions • Visual inspection/Surface defects • Guidewire compatibility • Hub attachment force test • Sheath peel/peel-ability test • Sheath tab tensile test • Sheath/VOC compatibility test • Sheath/hemostasis plug interface • ISO-594-2 Luer Testing • Radio-detectability • Dilator/Guidewire transition • Tip taper • Tip stiffness • Kink • Sheath/hemostasis plug interface • VOC placement through sheath • Sheath Peelability • Visual Inspection – Packaging • Dye Penetration – Packaging • Underwater Bubble Emission Testing – Packaging • Tensile Strength – Packaging

	• Internal Burst Pressure
Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject HeRO Graft and HeRO Graft Accessory Component Kit meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the HeRO Graft and HeRO Graft Accessory Component Kit K203724.