May 25, 2021

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

Re: K203724
Trade/Device Name: Merit HeRO Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: DSY, MSD, LJS
Dated: April 15, 2021
Received: April 16, 2021

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)*
K203724

Device Name
Merit 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.

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

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5.0 TRADITIONAL 510(K) SUMMARY

Submitted by:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095
Contact Person:	Susan Christensen Telephone (801) 208 4789 Email suchristensen@merit.com
Date of Summary:	25 MAY 2021
Trade or Proprietary Name:	Merit HeRO® Graft
Common or Usual Name:	Vascular Graft Prosthesis
Classification Name:	Prosthesis, Vascular Clamp, of 6mm and greater diameter
Regulation Number	21 CFR 870.3450
Classification:	Class II
Product Code:	DSY, MSD, LJS
Review Panel:	Cardiovascular
Predicate Device:	HeRO Graft, K172637

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), (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 ACK (a convenience kit) contains instruments that aid in the implantation of the HeRO Graft including, introducers, dilators, delivery stylet, 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.

Intended Use:

The HeRO® Graft is intended use in maintaining long term vascular access for chronic hemodialysis patients who have exhausted venous access sites suitable for fistulas or grafts.

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[1] 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.[2]

[1]Vascular Access Work Group. National Kidney Foundation KDOQI clinical practice guidelines for vascular access. Guideline 1: patient preparation for permanent hemodialysis access. *Am J Kidney Dis* 2006;48(1Suppl1):S188-91.

[2]Hemodialysis Adequacy 2006 Work Group. National Kidney Foundation KDOQI clinical practice guidelines for hemodialysis adequacy, update 2006. *Am J Kidney Dis* 2006;48(Suppl 1):S2-S90.

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 is similar in design and technological characteristics to the predicate HeRO Graft device.

The comparison between the subject device and predicate device is based on the following:

- Same Clinical use
- Same Indications for use
- Same Basic Design
- Same fundamental technology/principle of operation
- Same Labeling
- Same Packaging
- Same Sterilization Methods
- Same Intended Use

The following technological differences exist between the subject device and predicate device:

- Different (similar) material types
- Dimensional differences

Technological Characteristics:

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 meets the acceptance criteria established by the standards as they apply to device safety and efficacy.

FDA Guidance for Industry and FDA Staff: Guidance Document for Vascular Prostheses 510(k) Submissions, Nov 1, 2000

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 7198, *Cardiovascular implants and extracorporeal systems – Vascular prostheses – Tubular vascular grafts and vascular patches.*

ISO 11135, *Sterilization of health care products –Ethylene oxide – Requirements for the development, validation and routing 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 10993-3, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*

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 10993-10, *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*

ISO 10993-17, *Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substance*

ISO 10993-18, *Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process*
ASTM F756, *Standard Practice for Assessment of Hemolytic*

Properties of Materials

United States Pharmacopeia, National Formulary 37, General Chapter <151>, Pyrogen Test.

The following performance data were provided in support of the substantial equivalence determination.

Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the HeRO Graft 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
- Genotoxicity
- Thrombogenicity
- Complement Activation
- Implantation and Subacute/Subchronic toxicity
- Chemical Characterization

The HeRO Graft met the biocompatibility requirements for implant device with tissue and circulating blood contact for a permanent (> 30 days) duration.

The following performance tests were conducted to support substantial equivalence:

Performance Testing:

- Dimension Verification
- Longitudinal Tensile Strength
- Pressurized Burst Strength
- Kink Diameter

- Microscopic Porosity
- Water Entry Pressure
- Integral Water Permeability
- Clamp Leakage
- Suture Retention Strength
- Beading Peel Strength
- Strength after Repeated Puncture

Design Validation Testing:

- Guideline Acceptability
- Kink Resistance
- Handling
- Cutting
- Syringe Adapter Compatibility
- Suturability

Animal Study:

In the animal study, 18 sheep were implanted with a test article and a control article. There were no premature deaths related to the test article or control article. The three (3) time points for the chronic study were Group 1, 30-day, Group 2, 90-day, and Group 3, 180-day.

Per angiographic and histopathologic evaluations, the test articles demonstrated equal to or better patency, stenosis, thrombogenicity, cell and tissue response when compared to the control articles at termination on day 30, 90 and 180. The test article exhibited a favorable overall biological response when compared to the control article.

Per pathology of non-target organs (e.g., brain, lungs, kidneys, spleen, heart, and liver), there were no adverse clinical sequalae and no animal mortality related to the presence of the test article.

The Merit test article was as safe and performed as well as the control article.

Summary of Substantial Equivalence

Based on the indication for use, design, safety, and performance testing, the subject HeRO Graft meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the HeRO Graft K172637.