November 30, 2017

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

Re: K172637
Trade/Device Name: Merit HeRO Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY, LJS, MSD
Dated: August 31, 2017
Received: September 1, 2017

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. 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,

Nicole G. Ibrahim -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)*
K172637

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[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.

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.

510(k) Summary K172637

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) 253-6919 Susan Christensen August 31, 2017 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Merit HeRO® Graft Vascular Graft Prosthesis Prosthesis, Vascular Graft, of 6mm and Greater Diameter II DSY, LJS, MSD 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 K124039 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), (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 attached to a custom titanium alloy connector. 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, vascular 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[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]

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[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 purpose of this 510(k) notification is to: modify the radiopaque marker band and silicone material of the VOC; and qualify additional grafts for use with the Adapter.

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

- Clinical use
- Indications for use
- Basic Design
- Material types that meet ISO 10993
- Fundamental technology/principle of operation
- Labeling
- Packaging
- Sterilization methods
- Intended use

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 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"
- FDA Guidance Document: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, Dec 11, 2014
- ISO 10555-1, Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements
- 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 10993-6, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
- 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, Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2119 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

- ASTM F2182 Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants during Magnetic Resonance Imaging
- ASTM F2213 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- United States Pharmacopeia, National Formulary 30, General Chapter <151>, Pyrogen Test.

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

Performance Data (Continued)

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.

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

The results of the following performance tests demonstrated that the subject device met the acceptance criteria applicable to the safety and efficacy of the device.

Performance Testing-

- Dimensions
- Leakage
- Tensile – Attachment Strength
- Corrosion Resistance
- Clamp Resistance
- Kink Assessment
- Pressurized Inner Diameter
- Stiffness
- Body Crush Resistance
- V-Bend Flex Fatigue
- Burst Resistance
- Tip Recovery
- Marker Band Retention
- Radiopacity
- Sheath Delivery/Pushability
- MRI Compatibility
- Graft Expander Compatibility
- Visual Inspection
- VOC Connection to Adapter/Connector

Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject device raises no new questions of safety or effectiveness compared to the predicate device and is substantially equivalent to the predicate device, the HeRO Graft K124039.