



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2016

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

Re: K151967
Trade/Device Name: Merit Centros® and CentrosFLO® Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Catheter, Hemodialysis, Implanted
Regulatory Class: II
Product Code: MSD
Dated: February 24, 2016
Received: February 25, 2016

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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" (21CFR 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 yours,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known)

K151967

Device Name

Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter

Indications for Use (Describe)

The Merit Centros and CentrosFLO Long-Term Hemodialysis Catheter are indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. This catheter is indicated for > 30 days, (long-term) placement.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

General Provisions	Submitter Name: Merit Medical Systems, Inc. Address: 1600 West Merit Parkway South Jordan, UT 84095 Telephone Number: (801) 208-4789 Fax Number: (801) 253-6919 Contact Person: Susan Christensen Date of Preparation: July 15, 2015 Registration Number: 1721504
Subject Device	Trade Name: Merit Centros® and CentrosFLO® Long-Term Hemodialysis Catheter Common/Usual Name: Implanted Hemodialysis Catheter Classification Name: Catheter, Hemodialysis, Implanted Regulatory Class: II Product Code: MSD 21 CFR §: 876.5540 Review Panel: Gastroenterology/Urology
Predicate Device	Trade Name: Merit Centros®/CentrosFLO® Long-Term Hemodialysis Catheter Classification Name: Catheter, Hemodialysis, Implanted Premarket Notification: K141363 Manufacturer: Merit Medical Systems, Inc. This predicate has not been subject to a design-related recall
Reference Device	No reference devices were used in this submission.
Device Description	<p>The Centros and CentrosFLO Long-Term Hemodialysis Catheters are dual lumen, 15FR catheters available in lengths ranging from 15 to 31 cm (cuff-to-tip). The catheter comes with a stiffening stylet that can be used for over-the-wire placement. The catheter lumens are D-shaped and made from radiopaque polyurethane. The distal end design is a fixed length pre-formed split-tip, with (CentrosFLO) or without (Centros) side-holes. The distal venous lumen extends past the arterial lumen, and includes a guide wire slit for insertion by the optional over-the-wire placement technique. The proximal device contains a fixed polyester cuff, an integrated bifurcation, suture wing, and extension legs with color coded occlusion clamps and Luer connectors (red and blue for the arterial and venous lumens respectively). The lumen priming volumes are printed on ID tags within the occlusion clamps. The trade name and cuff-to-tip length are printed on the catheter bifurcation. The catheter is a single-use device provided sterile via ethylene oxide for long-term (> 30 days) use.</p> <p>The Centros and CentrosFLO Long-Term Hemodialysis Catheters are marketed with any of the following components, depending on the product configuration: stylet, introducer, dilator(s), tunneler with sheath, introducer needle, scalpel, guide wire, adhesive wound dressings, injection caps, and spacer.</p>

Indications for Use	<p>The Merit Centros and CentrosFLO Long-Term Hemodialysis Catheter are indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. This catheter is indicated for > 30 days, (long-term) placement.</p> <p>There is no change in the Indications for Use Statement from the predicate to the subject device.</p>
Comparison to Predicate Device	<p>Providing long-term vascular access for hemodialysis and apheresis is the technological principle for both the subject and predicate device.</p> <p>At a high level, the subject and predicate devices are based on the following same technological elements:</p> <p>Design Indications for Use Kit Components Packaging Labeling Sterilization</p> <p>The following technological differences exist between the subject and predicate devices:</p> <p>The material formulations are different. The design of the bifurcation is changing slightly. Addition of spacer component to the full kit configuration.</p>
Performance Data	<p>FDA guidance and recognized performance standards have been established for Implanted Blood Access Devices for Hemodialysis under Section 514 of the Food, Drug and Cosmetic Act. A battery of tests was performed based on the requirements of the below recognized performance standards and draft guidance, as well as biocompatibility, sterilization, and labeling standards and guidance. Conformity to these standards demonstrates that the proposed Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter met the standards' established acceptance criteria applicable to the safety and efficacy of the device. Performance testing was conducted based on the risk analysis and based on the requirements of the following international standards/documents:</p> <ul style="list-style-type: none"> • FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, 1995 • FDA Draft Guidance for Industry and Food and Drug Administration Staff – Class II Special Controls Guidance Document Implanted Blood Access devices for Hemodialysis June 28, 2013 • ISO 10555-1:2013, Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements. • ISO 10555-3:2013, Sterile, Single-Use Intravascular Catheters, Part 3: Central Venous Catheters. • ISO 594-1:1986, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements. • ISO 594-2:1998, Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock fittings

**Performance
Data cont.**

- ISO 11135:2014, Sterilization of health care products –Ethylene oxide-Requirements for validation and routine control of a sterilization process for medical devices
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*
- FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995
- ISO 10993-3:2003, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*
- ISO 10993-4:2002 (Amd.1:2006), *Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood*
- ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-6:2007, *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
- ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
- ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ISO 10993-18:2005, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*
- ASTM F756-08:2008, *Standard Practice for Assessment of Hemolytic Properties of Materials*
- United States Pharmacopeia 36, National Formulary 31, 2013 <151> Pyrogen Test

The biocompatibility evaluation for the Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, 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 Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter met the biocompatibility requirements for externally communicating device with circulating blood contact for a permanent (> 30 days) duration.

The results of the testing demonstrated that the subject Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter met the acceptance criteria applicable to the safety and efficacy of the device.

**Summary of
Substantial
Equivalence**

Based on design qualification through safety and performance testing, the subject Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter meets the requirements that are considered essential for its intended use and supports substantial equivalence to the predicate device, the Merit Centros/CentrosFLO Long-Term Hemodialysis Catheter, K141363.