December 14, 2021

Merit Medical Systems, Inc.
Jennifer Webb
Regulatory Affairs Manager
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K212675
Trade/Device Name: Aspira Peritoneal Drainage System
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: PNG
Dated: November 16, 2021
Received: November 18, 2021

Dear Jennifer Webb:

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. However, you are responsible to determine that the medical devices you use as components in the kit 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, 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,

Glenn B Bell, Ph.D.
Director
THT3A1: Renal, Gastrointestinal,
Obesity and Transplantation Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212675

Device Name
Aspira Peritoneal Drainage System

Indications for Use *(Describe)*
The Aspira Peritoneal Drainage System is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

•Aspira Drainage Catheter: The Aspira Drainage catheter is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieves symptoms such as dyspnea or other symptoms associated with malignant ascites.
•Aspira Drainage Bag: The Aspira Drainage Bag is indicated for use only with the Aspira Valve Assembly for intermittent drainage.
•Aspira Drainage Bottle: The Aspira Drainage Bottle is indicated for use only with the Aspira Valve Assembly for intermittent drainage.
•Aspira Dressing Kit: The Aspira Dressing Kit is indicated for dressing of the drainage catheter and exit site.
•Aspira Valve Assembly / Repair Kit: The Aspira Valve Assembly is indicated for use with Aspira, Asept®, PleurX® and Rocket® catheters.
•Aspira Luer Adapter: The Luer Adapter is intended to provide access to the Aspira Valve Assembly. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe, or other appropriate method.
•Aspira Universal Tubing Adapter: The Universal Tubing Adapter is intended to provide access to the Aspira Valve Assembly. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe,or other appropriate method.

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

General Provisions	Submitter Name: Address: Telephone Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems Inc. 1600 West Merit Parkway South Jordan UT 84095 (801) 208-4247 Jennifer Webb 20 Aug 2021 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Aspira Peritoneal Drainage System Tunneled drainage catheter system Peritoneal Dialysis System and Accessories Ascites, Long-Term Indwelling 2 PNG 876.5630 Gastroenterology/Urology
Predicate Device	Trade Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel: Premarket Notification: Manufacturer:	Aspira Peritoneal Drainage System Peritoneal Dialysis System and Accessories Ascites, Long-Term Indwelling 2 PNG 876.5630 Gastroenterology/Urology K110396 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	The Aspira Peritoneal Drainage System provides patients with a convenient method to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites at home. The primary components of the Aspira Peritoneal Drainage System are the Aspira Peritoneal Drainage Catheter, the Aspira Drainage Bag, and the Aspira Drainage Bottle.	
Intended Use	The Aspira Peritoneal Drainage System is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.	

Indications for Use	• Aspira Drainage Catheter: The Aspira Drainage catheter is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites. • Aspira Drainage Bag: The Aspira Drainage Bag is indicated for use only with the Aspira Valve Assembly for intermittent drainage. • Aspira Drainage Bottle: The Aspira Drainage Bottle is indicated for use only with the Aspira Valve Assembly for intermittent drainage. • Aspira Dressing Kit: The Aspira Dressing Kit is indicated for dressing of the drainage catheter and exit site. • Aspira Valve Assembly / Repair Kit: The Aspira Valve Assembly is indicated for use with silicone catheters with inner diameters between 0.103" - 0.116" such as Aspira, Asept®, PleurX® and Rocket® catheters. • Aspira Luer Adapter: The Luer Adapter is intended to provide access to the Aspira Valve Assembly. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe, or other appropriate method. • Aspira Universal Tubing Adapter: The Universal Tubing Adapter is intended to provide access to the Aspira Valve Assembly. It is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, syringe, or other appropriate method. The Indications for Use statement for the subject Aspira Peritoneal Drainage System device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.
Comparison to Predicate Device	Technological characteristics of the subject Aspira Peritoneal Drainage System are equivalent with respect to the basic catheter design and function to those of the predicate devices. Differences do not raise any new questions regarding safety and effectiveness. The design and technological characteristics of the subject device are substantially equivalent to those of the predicate device. The subject device has the same materials and use as the predicate device. The main difference between the subject and the predicate device is the expanded scope of the indications to expand the compatibility of the Aspira Valve/Repair Kit portion of the Aspira Peritoneal Drainage System with competitive drainage catheters as well as the introduction of the Aspira Drainage Bottle as an alternative to the Aspira Drainage Bag. At a high level, the subject and predicate devices are based on the following same technological elements: • Same Clinical Use • Same Intended Use • Same Materials

Comparison to Predicate Device (Cont.)

- Same Overall Device Design
- Same Sterilization Methods
- Same Labeling and Packaging
- Same Fundamental Technology/Principle of Operation

The following differences exist between the subject and predicate devices:

- Expanded Indications for use to include:
  - Compatibility of the Merit Aspira replacement valve used in the Aspira Repair Kit with competitive drainage catheters (Asept®, PleurX® and Rocket® catheters).

Use of the Aspira Drainage Bottle as an alternative to the Aspira Drainage Bag.

Safety & Performance Testing

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

Performance Testing-Bench

- Aspira Valve – Compatibility with Competitive Drainage Catheters (Aspira, Asept®, PleurX® and Rocket® catheters)
  - Catheter Leak Test – Negative Pressure
  - Tensile Strength – Valve Assembly to Catheter
  - Design Validation - Insertion Forces
- Aspira Drainage Bottle
  - 1000 mL Fluid Pull
  - Leak Test
  - Barb to Tubing
  - Tensile Tubing to Connector
  - Tensile Tubing
  - Impact Resistance
  - Human Factors Engineering/User Engineering Simulated Use
    - Drainage Speed Control
    - Bottle Emptying
    - Bottle Activation Force
    - Bottle Activation Method
    - Drainage Time
    - Indication of Full Flow
    - Intuitiveness of Status
    - Handle Reseal Ability
    - Grip Comfort when Empty
    - Grip Comfort when Full
    - IFU Understandability for Lay Users
    - Ease of Use
    - Vacuum Loss
    - Fluid Leak

The results of the testing demonstrated that the subject Aspira Peritoneal Drainage System met the predetermined acceptance criteria applicable to the safety and efficacy of the device.

Summary of Substantial Equivalence	Based on the design and safety and performance testing, the subject Aspira Peritoneal Drainage System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Aspira Peritoneal Drainage System, K110396 manufactured by Merit Medical Systems, Inc.