March 3, 2023

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

Re: K212696
Trade/Device Name: Aspira Pleural Drainage System
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: Class II
Product Code: DWM
Dated: January 31, 2023
Received: February 1, 2023

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. 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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K212696

Device Name
Aspira Pleural Drainage System

Indications for Use *(Describe)*
The Aspira Pleural Drainage System is intended for long-term intermittent drainage of pleural fluid accumulated in the pleural cavity forth purpose of relieving symptoms associated with pleural effusion.

• Aspira Drainage Catheter: The Aspira Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions. The catheter is intended for long-term access of the pleural cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusions and other recurrent effusions.

• 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 the 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.

510(k) Summary (K212696)

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) 208-4403 Desiree Bond 02 Mar 2023 1721504
Subject Device	Trade Name: Classification Regulatory Class: Product Code: Regulation Number: Premarket Notification: Manufacturer:	Aspira Pleural Drainage System Apparatus, Suction, Patient Care Class II DWM 21 CFR 870.5050 K212696 Merit Medical Systems, Inc.
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: This predicate has not been subject to a design-related recall.	Aspira Pleural Drainage System Apparatus, Suction, Patient Care K110409 Merit Medical Systems, Inc.
Reference Device	PleurX Catheter: PN 50-7510 (K201155; K160450)	
Device Description	The Aspira Pleural Drainage System provides patients with a convenient method to relieve pleural effusion symptoms at home. The primary components of the Aspira Pleural Drainage System are the Aspira Pleural Drainage Catheter, the Aspira Drainage Bag, and the Aspira Drainage Bottle.	
Intended Use	The Aspira Pleural Drainage System is intended for long-term intermittent drainage of pleural fluid accumulated in the pleural cavity for the purpose of relieving symptoms associated with pleural effusion.	
Indications for Use	The Aspira Pleural Drainage System is intended for long-term intermittent drainage of pleural fluid accumulated in the pleural cavity for the purpose of relieving symptoms associated with pleural effusion. • Aspira Drainage Catheter: The Aspira Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions. The catheter is intended for long-term access of the pleural cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusions and other recurrent effusions. • 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.	

Indications for Use (Cont.)	• Aspira Valve Assembly / Repair Kit: The Aspira Valve Assembly is indicated for use with inner diameters between 0.103" - 0.116 such as the 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 Pleural 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: intended for long-term intermittent drainage of pleural fluid accumulated in the pleural cavity for the purpose of relieving symptoms associated with pleural effusion.
Comparison to Predicate Device	Technological characteristics of the subject Aspira Pleural 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 Pleural 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 • 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 silicone catheters with inner diameters between 0.103" - 0.116, including competitive drainage catheters such as Asept®, PleurX® and Rocket® catheters. • Use of the Aspira Drainage Bottle as an alternative to the Aspira Drainage Bag.

Performance Data	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Aspira Pleural Drainage System was conducted based on the risk analysis and based on the requirements of the following international standard(s): <u>Labeling</u> • ISO 15223-1:2016, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements <u>Sterility</u> • ASTM F2250-13:2018, Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials • ASTM F2252/F2252M-13:2018, Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape • ISO 11135:2014, Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization • AAMI TIR28:2016, Product Adoption and process equivalency for ethylene oxide sterilization • ISO 14644-1:2015, Classification of Air Cleanliness, Clean rooms & Associated Controlled Environments. Part 1: Classification of air cleanliness • ISO 14644-2:2015, Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration • ISO 11737-1:2018, Sterilization of medical devices -- Microbiological methods – Part 1: Determination of a population of microorganisms on product • ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals <u>Biological Safety</u> • ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing • ISO 10993-3:2014, Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity • ISO 10993-5:2015, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity • ISO 10993-10:2014, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization • ISO 10993-11:2017, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity • ISO 10993-12:2021, Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials • ISO 10993-18:2020, Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process • ISO 10993-19:2020, Biological evaluation of medical devices — Part 19: Physio-chemical, morphological, and topographical characterization of materials • ISO 10993-23:2021, Biological evaluation of medical devices — Part 23: Tests for irritation • ASTM F2475-11:2020, Standard Guide for Biocompatibility of Medical Device Packaging Materials <u>Device/Design</u> • ISO 594-1:1986, Conical Fittings with 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 1: General Requirements
Performance Data (Cont.)	

Performance Data (Cont.)	• ISO 594-2:1998, Conical Fittings with 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings • ISO 80369-7:2017, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications • ISO 20697:2018, Sterile drainage catheters and accessory devices for single use • ISO 10079-3:2014, Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source • ASTM F640:20, Standard test methods for radiopacity of plastics for medical use <u>Packaging</u> • ISO 11607-1:2019, Packaging for Terminally Sterilized Medical Devices. Part 1: Requirements for materials, sterile barrier systems, and packaging systems • ISO 11607-2:2019, Packaging for Terminally Sterilized Medical Devices. Part 2: Validation requirements for forming, sealing and assembly processes • ISO 2233:2001, Packaging -- Complete, filled transport packages and unit loads -- Conditioning for testing • ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems • ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) • ASTM F1929-15, Standard Test Method for Detecting Seal Leaks in porous Medical Packaging by Dye Penetration • ASTM F88/F88M- 15, Standard Test Method for Seal Strength of Flexible Barrier Materials • ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices <u>Quality</u> • ISO 14971:2019, Medical Devices - Application of Risk Management to Medical Devices • IEC 62366-1:2015, Medical Devices – Application of usability engineering to medical devices • ISO 13485:2016, Quality Systems – Medical Devices – Quality Management Systems. Requirements for Regulatory Purposes The following performance data were provided in support of the substantial equivalence determination. <u>Biocompatibility testing</u> All patient contacting portions of the subject Aspira Pleural Drainage System are identical to the predicate Aspira Pleural Drainage System (K110409). The Aspira Drainage Bottle has been categorized as a non-patient contacting component and therefore no additional biocompatibility testing was required per 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'" September 2020 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. <u>Performance Testing-Bench</u> • Aspira Valve – Compatibility with Competitive Drainage Catheters (Aspira,

Performance Data (Cont.)	Asept®, PleurX® and Rocket® catheters) ○ Catheter Leak Test – Negative Pressure ○ Tensile Strength – Valve Assembly to Catheter ○ Design Validation - Insertion Forces • Aspira Drainage Bottle ○ Component Deformation Under Vacuum ○ Tensile Barb to Tubing ○ Tensile Tubing to Connector ○ Tensile Tubing ○ Impact Resistance ○ Suction Source Impact Resistance ○ Leak Test ○ 1000 mL Fluid Pull ○ 1000 mL Fluid pull rate ○ Tensile Valve to tubing ○ Human Factors Engineering/User Engineering Simulated Use ▪ Vacuum Loss ▪ Fluid Leak ▪ 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 Packaging The packaging configuration of the subject device will not change from the packaging configuration of the device as it is currently marketed. However, an additional packaging configuration has been qualified to conform to standard ISO 11607-1: 2006 Packaging for terminally sterilized medical devices and ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems. • Visual Inspection • Seal Strength / Burst Testing The results of the testing demonstrated that the subject Aspira Pleural 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 Pleural Drainage System meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Aspira Pleural Drainage System, K110409 manufactured by Merit Medical Systems, Inc.