August 18, 2023

Pleural Dynamics, Inc.
% Joseph Ostendorf
Regulatory Affairs Consultant
Ostendorf Consulting, LLC
23879 Blue Spruce Road
Sauk Centre, Minnesota 56378

Re: K231096
Trade/Device Name: Automatic Continuous Effusion Shunt (ACES) System
Regulation Number: 21 CFR 876.5955
Regulation Name: Peritoneo-Venous Shunt
Regulatory Class: Class II
Product Code: KPM
Dated: July 27, 2023
Received: July 27, 2023

Dear Joseph Ostendorf:

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,

Glenn B. Bell -S

for Gema Gonzalez
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K231096

Device Name
Automatic Continuous Effusion Shunt (ACES) System

Indications for Use *(Describe)*
The Automatic Continuous Effusion Shunt (ACES) System is indicated for use in adult (>21 years of age) patients with
• chylothorax
• intractable aseptic pleural effusion

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
*PRAStaff@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."*

# Pleural Dynamics, Inc.
# 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

| | |
|---|---|
| **510(k) Number:** | K231096 |
| **Date Prepared:** | August 17, 2023 |
| **Applicant:** | Pleural Dynamics, Inc.<br>952 Medina Road<br>Wayzata, MN 55391<br>+1 (763) 501-7223 |
| **Contact Person:** | Joseph Ostendorf<br>Regulatory Affairs Consultant<br>23879 Blue Spruce Road<br>Sauk Centre, MN 56378 |

**SUBJECT DEVICE**

| | |
|---|---|
| **Trade/Device Name:** | Automatic Continuous Effusion Shunt (ACES) System |
| **Device Regulation Number:** | 21 CFR § 876.5955 |
| **Device / Regulation Name:** | Peritoneo-venous shunt |
| **Regulation Description / Common Name:** | Shunt, Peritoneal |
| **Product Code:** | KPM |
| **Device Class / Regulation Classification:** | Class II |

**DEVICE DESCRIPTION (For the Device Subject to this 510(k) Premarket Notification)**

The ACES System is an implanted pleural-peritoneal shunt system intended to palliate symptoms of recurrent pleural effusion, an accumulation of fluid in the cavity around the lungs.

The ACES System comprises a pump that is, generally, a resilient flexible bulb having an inlet and an outlet. The inlet is attached to a first fenestrated barium striped tube that extends from the inlet valve to the patient's pleural cavity. The outlet is connected to a second fenestrated barium striped tube that extends from the outlet valve to the patient's peritoneal cavity. Each one-way valve is connected to a single pump chamber with an internal automatic pump extension and external manual compression pump extension and an integrated implant securement flange for suture fixation in the muscular facia. In use, the internal (intercostal) automatic (passive) pump extension is placed between adjacent ribs in the patient and the external (subdermal) manual compression (active) pump extension is positioned under the skin and external to the ribs.

Using a patient's own respiration, the internal automatic pump extension operates by being successively compressed and decompressed between adjacent ribs, as the patient breathes, whereby pumping the fluid from the pleural cavity to the peritoneal cavity, where it is naturally reabsorbed by the body. The external manual compression pump extension allows for intraprocedural priming of the pump chamber as well as manual compression by the patient, post procedurally, at will or as directed by their physician for movement of fluid from the pleural cavity to the peritoneal cavity.

**INDICATIONS FOR USE (For the Device Subject to this 510(k) Premarket Notification)**

The Automatic Continuous Effusion Shunt (ACES) System is indicated for use in adult (>21 years of age) patients with

- chylothorax
- intractable aseptic pleural effusion

**DEVICE CLASSIFICATION, INTENDED USE/INDICATIONS FOR USE, AND TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS COMPARISONS**

The following tables provide a side-by-side comparison of the ACES System to the predicate and reference devices to support this pre-market notification.

| **Device Classification Comparison** | | | | |
|---|---|---|---|---|
| | **Subject Device K231096** | **Predicate Device K822686** | **Reference Device K012235** | **Reference Device K912645** |
| **Trade/Device Name:** | Automatic Continuous Effusion Shunt (ACES) System | Denver Peritoneo-Venous Shunt | Denver Pleural Effusion Shunt and Denver Pleural Effusion Shunt with External Pump Chamber | Atriums PDR Thoracic Catheter |
| **Regulation Medical Specialty** | Gastroenterology / Urology | Gastroenterology / Urology | Gastroenterology / Urology | General & Plastic Surgery |
| **Device Regulation Number:** | 21 CFR § 876.5955 | 21 CFR § 876.5955 | 21 CFR § 876.5955 | 21 CFR § 878.4200 |
| **Device / Regulation Name:** | Peritoneo-venous shunt | Peritoneo-venous shunt | Peritoneo-venous shunt | Introduction/drainage catheter and accessories |
| **Regulation Description / Common Name:** | Shunt, Peritoneal | Shunt, Peritoneal | Shunt, Peritoneal | Catheter, Ventricular, General & Plastic Surgery |
| **Product Code:** | KPM | KPM | KPM | GBS |
| **Device Class / Regulation Classification:** | Class II | Class II | Class II | Class I |

| Intended Use/Indications for Use Comparison | | | | |
|---|---|---|---|---|
| | **Subject Device K231096** | **Predicate Device K822686** | **Reference Device K012235** | **Reference Device K912645** |
| **Intended Use** | The Automatic Continuous Effusion Shunt (ACES) System is intended to move fluid from one location in the body to another. | The Denver Peritoneo-Venous Shunt is intended to move fluid from one location in the body to another. | The Denver Pleural Effusion Shunt is intended to move fluid from one location in the body to another. | The Atriums PDR Thoracic Catheter is intended to allow movement of fluid from the body. |
| **Indications for Use** | The Automatic Continuous Effusion Shunt (ACES) System is indicated for use in adult (>21 years of age) patients with<br>• chylothorax<br>• intractable aseptic pleural effusion | Unknown | The Denver Pleural Effusion Shunt is indicated for use in patients with<br>• chylothorax<br>• intractable aseptic pleural effusion<br>The Denver Pleural Effusion Shunt with External Pump Chamber is indicated for adult, pediatric, and neonatal patients with<br>• chylothorax<br>• intractable aseptic pleural effusion | Atrium thoracic catheters are intended to facilitate the evacuation of air and/or fluid from the chest cavity or mediastinum. |

| Technological and Performance Characteristics Comparison | | | | |
|---|---|---|---|---|
| | **Subject Device K230196** | **Predicate Device K822686** | **Reference Device K012235** | **Reference Device K912645** |
| **Manufacturer** | Pleural Dynamics, Inc. | BD (Becton, Dickinson and Company) | BD (Becton, Dickinson and Company) | Atrium Medical Corporation (MAQUET Cardiovascular, LLC) |
| **Construct** | Single Pump Chamber with Double Valves and Pleural and Peritoneal Limbs | Single Pump Chamber with Valves with Peritoneal and Venous Limbs | Single Pump Chamber with Double Valves and Pleural and Peritoneal Limbs | Single Limb Tube |
| **Materials of Construction** | Pump Chamber: Silicone<br>Limbs: Silicone with Barium Sulfate Stripe | Pump Chamber: Silicone<br>Limbs: Silicone with Barium Sulfate Stripe | Pump Chamber: Silicone<br>Limbs: Silicone with Barium Sulfate Stripe | Limb: Silicone or Polyvinyl Chloride with Radiopaque Stripe |
| **Surface Treatment** | Yes – Covalently Bonded Heparin Coating | Yes – Ionically Bonded Heparin | None Known | Yes – Covalently Bonded Heparin Coating |

| Technological and Performance Characteristics Comparison | | | | | |
|---|---|---|---|---|---|
| | | **Subject Device K230196** | **Predicate Device K822686** | **Reference Device K012235** | **Reference Device K912645** |
| **Placement Technique** | | Seldinger Technique | Seldinger Technique | Seldinger Technique | Surgical Technique |
| **Design Intent** | | Placed internally, relative to the skin, with an extension of the pump chamber positioned between adjacent ribs to manage pleural effusion by moving fluid from the pleural cavity to the peritoneal cavity. | Placed internally or externally, relative to the skin, with a portion of the peritoneal tube positioned across the abdominal wall to manage ascites by moving fluid from the peritoneal cavity to the venous system. | Placed internally or externally, relative to the skin, with a portion of the pleural tube positioned between adjacent ribs to manage pleural effusion by moving fluid from the pleural cavity to the peritoneal cavity. | Placed partially internal and partially external, relative to the skin, with a portion of the tube positioned between adjacent ribs to drain the cavity by moving fluid or air from the pleural cavity to exterior of the body. |
| **Principles of Operation** | | Pleural effusion shunts are permanently placed drainage management systems designed to move fluid from the pleural cavity to the peritoneal cavity. | Peritoneo-Venous shunts are permanently placed drainage management systems designed to move fluid from the peritoneal cavity to the venous system. | Pleural effusion shunts are permanently placed drainage management systems designed to move fluid from the pleural cavity to the peritoneal cavity. | Thoracic catheters are temporarily placed access devices designed to move fluid from the thorax to the exterior of the body. |
| **Tubing Length** | | 30 cm | Unknown | Unknown | Unknown |
| **Tubing Inner Diameter** | | 2.64 mm | Unknown | Unknown | Unknown |
| **Tubing Outer Diameter** | | 4.88 mm | Unknown | Unknown | Unknown |
| **Pump Fluid Flow Rate** | **Automatic** | 250 – 750 mL/day | N/A | N/A | N/A |
| | **Manual** | Approximately 2 mL per complete pump compression | Unknown | Approximately 2 mL per complete pump compression | N/A |
| **Implantable** | | Yes | Yes | Yes | Yes |
| **Single Patient Use** | | Yes | Yes | Yes | Yes |
| **Design Prevents Backflow** | | Yes | Yes | Yes | No |
| **Biocompatible** | | Yes | Yes | Yes | Yes |
| **Provided Sterile** | | Yes | Yes | Yes | Yes |

**SUMMARY OF PERFORMANCE TESTING AND STANDARDS**

Performance testing was conducted to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate and reference devices, where applicable. A comparison was made against the predicate and reference devices, where data was available. The ACES System has undergone bench, biocompatibility, packaging, and sterilization testing to demonstrate the differences in technological characteristics do not raise different questions of safety and effectiveness.

| **Non-Clinical Performance Tests** | | |
|---|---|---|
| **Test** | **Test Method Summary** | **Results and Conclusions** |
| **Simulated Use** | Visual Inspection | Pass – All samples passed the acceptance criteria |
| | Pressure Testing | Pass – All samples passed the acceptance criteria |
| | Chamber Pumping (Automatic) | Pass – All samples passed the acceptance criteria |
| | Bulb Pumping (Manual) | Pass – All samples passed the acceptance criteria |
| | Chamber Flowrate (Automatic) | Pass – All samples passed the acceptance criteria |
| | Bulb Flowrate (Manual) | Pass – All samples passed the acceptance criteria |
| **Destructive** | Tensile | Pass – All samples passed the acceptance criteria |
| | Burst | Pass – All samples passed the acceptance criteria |
| **Backflow** | Backflow | Pass – All samples passed the acceptance criteria |
| **Securement** | Suture Pull Out Force | Pass – All samples passed the acceptance criteria |
| **Coating** | Vertical Pinch Test | Pass – All samples passed the acceptance criteria |
| | Coating Length Verification | Pass – All samples passed the acceptance criteria |
| | Toluidine Blue & Finger Rub Test | Pass – All samples passed the acceptance criteria |
| **Packaging** | The packaged device and labeling shall withstand the conditions of ISTA 3A and ASTM D-4169; DC13; AL1 without loss of function, sterility, or legibility. | Pass – All samples passed the acceptance criteria |
| **Shelf-Life** | The packaged device and labeling shall withstand simulated storage conditions without loss of function, sterility, or legibility. | Pass – All samples passed the acceptance criteria |
| **Sterilization** | The sterilization process shall be validated to demonstrate a minimum of SAL of $10^{-6}$ for the product using Gamma radiation. | Pass – All samples passed the acceptance criteria |

| Biocompatibility | | |
|---|---|---|
| **Test** | **Test Summary** | **Conclusions** |
| **Cytotoxicity** | MEM Elution Cytotoxicity Assay (ISO)<br>(GLP) | Pass – Non-cytotoxic |
| **Sensitization** | Guinea Pig Maximization Test (ISO) Sensitization<br>(GLP - 2 Extracts) | Pass – Non-sensitizer |
| **Irritation or Intracutaneous Reactivity** | Intracutaneous Reactivity Test (ISO)<br>(GLP - 2 Extracts) | Pass – Non-irritant |
| **Material Mediated Pyrogenicity** | Material Mediated Pyrogenicity Test (ISO/USP)<br>(GLP) | Pass – Non-pyrogenic |
| **Acute Systemic Toxicity** | Acute Systemic Toxicity Test (ISO)<br>(GLP - 2 Extracts) | Pass – Non-toxic |
| **Subacute/Subchronic Toxicity** | (31-Day) Systemic Toxicity (Implant Method) and Implant Evaluation Test in Rabbits (ISO) | Pass – No systemic toxic effects were observed<br>Pass – Sight reaction observed |
| **Implantation Effects** | (91-Day) Systemic Toxicity (Implant Method) and Implant Evaluation Test in Rabbits (ISO) | Pass – No systemic toxic effects were observed<br>Pass – Slight reaction observed |
| **Genotoxicity** | Ames Bacterial Reverse Mutation Assay (ISO)<br>(GLP - 2 Extracts) | Pass – Non-mutagenic |
| | Mouse Lymphoma Assay (ISO)<br>(GLP - 2 Extracts) | Pass – Non-mutagenic |
| **Chronic Toxicity** | Not evaluated | The biocompatibility of the Automatic Continuous Effusion Shunt System has been evaluated to support an implant duration of 12 months, beyond which point it is recommended the device be removed. |
| **Carcinogenicity** | | |

**BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE**

The Device Classification, Intended Use, and elements of the Fundamental Scientific Technology for the ACES System are the same as those described for the Predicate Device (K822686). The Surface Treatment is the same as that of the Reference Device (K912645). The Indications for Use and Principle of Operation is the same as that of the Reference Device (K012235).

The ACES System does not raise different questions regarding safety and effectiveness when compared to the predicate and reference devices and has been determined by Pleural Dynamics, Inc. to be substantially equivalent.

In summary, the ACES System has the same or similar following characteristics to the predicate and reference devices, which have previously received 510(k) clearance:

- Has the ***same*** device classification (Predicate Device K822686)
- Has the ***same*** intended use (Predicate Device K822686)
- Has the ***similar*** indications for use (Reference Device K012235)
- Uses ***similar*** technological and performance characteristics (Reference Device K012235)
- Uses the ***similar*** principles of operation (Reference Device K012235)
- ***Same*** special controls are met (Predicate Device K822686)

Therefore, the conclusions drawn from the non-clinical tests demonstrate the device is as safe, as effective, and performs as well as the legally marketed device predicate, and reference devices, where applicable, per 21 CFR 807.92(b)(3). The ACES System is substantially equivalent to the predicate device and reference devices, where applicable.

**SUBSTANTIAL EQUIVALENCE CONCLUSIONS**

Through the thorough comparison of technological and performance characteristics, the subject device is determined to be substantially equivalent to the predicate device.