September 3, 2021

Atrium Medical Corporation
Robin Mulvey
Senior Regulatory Affairs Specialist
40 Continental Blvd.
Merrimack, New Hampshire 03054

Re: K201305
Trade/Device Name: Auto transfusion (ATS) Chest Drains: Ocean Water Seal Chest Drain, Oasis Dry Suction Water Seal Chest Drain, Express Dry Seal Chest Drain
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: July 30, 2021
Received: August 4, 2021

Dear Robin Mulvey:

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,

Nicole Gillette
Acting Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K201305

Device Name
Auto transfusion (ATS) Chest Drains:
Ocean Water Seal Chest Drain, Oasis Dry Suction Water Seal Chest Drain, Express Dry Seal Chest Drain

Indications for Use *(Describe)*
• Evacuate air and/or fluid from the chest cavity or mediastinum.
• Help re-establish lung expansion and restore breathing dynamics.

Chest Drain Auto transfusion (ATS)
To facilitate collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in postoperative and trauma blood loss management.

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."

Section 5 510(K) Summary

Auto transfusion (ATS) Chest Drains 510(k) summary prepared in accordance with 21 CFR part 807.92

General information:

Submitter's name and address:	Atrium Medical Corporation 40 Continental Drive Merrimack, NH 03054
Registration Number:	3011175548
Contact Person:	Robin Mulvey Principal Regulatory Affairs Specialist Tel: 603.864.5424 Fax: 973.629.1325 email: robin.mulvey@getinge.com
Date Prepared:	May 13, 2020

Device Information:

Trade Name(s):	Auto transfusion (ATS) Chest Drains: Ocean Water Seal Chest Drain Oasis Dry Suction Water Seal Chest Drain Express Dry Seal Chest Drain
Common/Generic Name:	apparatus, Auto transfusion
Classification Name:	Auto transfusion apparatus
Regulation Number:	21 CFR 868.5830
Product Code:	CAC (Anesthesiology Device Panel)
Device Class:	The Auto transfusion (ATS) Chest Drains are classified as Class II devices in the US according to 21 CFR 868.5830

Predicate Device Information:

Atrium's Auto transfusion (ATS) Chest Drains: Ocean Water Seal Chest Drains, Oasis Dry Suction Water Seal Chest Drains and Express Dry Seal Chest Drains are substantially equivalent in function and intended use to the Express Chest Drain and Oasis Chest Drain (K043140) and Ocean Water Seal Chest Drain (K043582).

Device Description

Atrium's Auto transfusion (ATS) Chest Drains are sterile, single use, disposable devices that mimic a traditional "3 Bottle Systems".

A closed thoracic drainage system (chest drain and catheter together) are used to restore the chest to a more normalized condition after surgery, trauma, or spontaneous need for air and/or fluid to be removed. The Auto transfusion (ATS) features of the drains facilitate postoperative collection and reinfusion of autologous blood from the patient's pleural cavity or mediastinal area.

Intended Use

The Auto transfusion (ATS) Chest Drains are intended to evacuate air and/or fluid from the chest cavity (pleural spaces or mediastinum).

Indications for Use

- Evacuate air and/or fluid from the chest cavity or mediastinum.
- Help re-establish lung expansion and restore breathing dynamics.

  Chest Drain Auto transfusion (ATS)

  To facilitate collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in postoperative and trauma blood loss management.

Intended User/Operator

The primary intended users of the Auto transfusion Chest Drains; Ocean Water Seal Chest Drain, Oasis Dry Suction Water Seal Chest Drain and Express Dry Seal Chest Drain are surgeons, physicians, or nurses. Specifically, the primary intended users are chest medicine physicians, including but not limited to surgeons (cardiothoracic, general trauma, hepatobiliary, urology and other trained and qualified to treat conditions in the thorax requiring drainage), interventional physicians (pulmonology, radiology, anesthesiology, emergency medicine, critical care medicine, pain medicine and others trained and qualified to treat conditions in the thorax requiring drainage), physicians' assistants and certified nurse advanced practitioners or nurses who have been trained in the theoretical, technical, and clinical aspects of the use the devices.

Intended Use Environment

Auto transfusion Chest Drains; Ocean Water Seal Chest Drain, Oasis Dry Suction Water Seal Chest Drain and Express Dry Seal Chest Drain are used in a sterile environment (e.g. the surgical suite) or in a non-sterile environment (e.g. the Intensive Care Unit (ICU) or the Emergency Room (ER)) where a local sterile environment for procedures can be created.

Intended Patient

The target patient population is patients who need fluid and/or air evacuated from the chest cavity (pleural spaces or mediastinum). The actual choice of a specific drainage product is determined by the clinical indications and contraindications and the specific requirements of each patient's anatomy and physiologic condition as clearly described in the respective guides accompanying each device. The choice of device is at the sole discretion of the physician in charge of that patient.

Example Auto transfusion Drain

Technological characteristics:

Atrium's Auto transfusions (ATS) Chest Drains have the same technology and attributes as the predicate devices (K043140 and K043582).

Table 1: Technological Characteristics

Auto transfusions (ATS) Chest Drains Features	Ocean Water Seal Chest Drain	Oasis Dry Suction Water Seal Chest Drains	Express Dry Seal Chest Drain
Air Leak Monitor	√	√	√
Collection Chamber	√	√	√
Dry Suction Regulator		√	√
Easy-to-Grip Handle	√	√	√
In-Line Connector	√	√	√
Manual High Negativity Vent	√	√	√
Multi-Position Hangers	√	√	√
Needleless Access Port	√	√	√
Patient Connector	√	√	√
Patient Pressure Float Ball	√	√	√
Patient Tube	√	√	√
Patient Tube Clamp	√	√	√
Positive Pressure Release Valve	√	√	√
Suction Control Chamber	√		
Suction Monitor Bellows		√	√
Suction Port	√	√	√
Swing Out Floor Stand	√	√	√
Vacuum Indicator			√
Water Seal Chamber	√	√	
Ampoule, Water, 45ml		√	
Prefilled Syringe, 30ml			√

Major Materials of Construction:

Atrium's Auto transfusions (ATS) Chest Drains have the same Major Materials of Construction as the predicate devices (K043140 and K043582).

Table 2: Major Materials of Construction

Auto transfusions (ATS) Chest Drains Major Materials	Ocean Auto transfusion Drain	Oasis Ocean Auto transfusion Drain	Express Ocean Auto transfusion Drain
Acrylonitrile butadiene styrene (ABS)	√	√	√
Polyvinyl Chloride (PVC)	√	√	√
TPE/TPR Thermoplastic Elastomers (TPE)/ Thermoplastic Rubber (TPR)	√	√	√
High Density Polyethylene (HDPE)	√	√	√
Low-Density Polyethylene (LDPE)	√	√	√

Table 3 below demonstrates the equivelancy of the Auto transfusion (ATS) Chest drains subject of this submission against the Auto transfusion (ATS) Chest Drains subject of the predicate submissions K043140 and K043582.

Table 3: Summary Comparison to Predicates K043140 and K043582

Device Component	PREDICATES: K043140 K043582	Comparison
Filter, Screen, Blood Recovery Unit (BRU) 300CC Acrylonitrile butadiene styrene and Polysulfone (	Filter, Screen, Blood Recovery Unit (BRU) 300CC Acrylonitrile butadiene styrene and Polysulfone	Same as Predicate.
Sub Assembly, Drain, Blood Recover Unit (BRU) Polyisoprene, Low-Density Polyethylene, Cryolite acrylic, Acrylonitrile butadiene styrene, High Density Polyethylene	Sub Assembly, Drain, Blood Recover Unit (BRU), Ocean Polyisoprene, Low-Density Polyethylene, Cryolite acrylic, Acrylonitrile butadiene styrene, High Density Polyethylene	Same as Predicate.
Hanger, Drain, Flexible Nylon , white	Hanger, Drain, Flexible Nylon, white	Same as Predicate.
Stand, Chest Drain, Universal Acrylonitrile butadiene styrene (ABS), white	Stand, Chest Drain, Universal Acrylonitrile butadiene styrene (ABS), white	Same as Predicate.
Dye Ball - white W/blue dye Polypropylene ball	Dye Ball - white W/blue dye Polypropylene ball	Same as Predicate.
Spring, Manual Vent Valve 302 stainless steel	Spring, Manual Vent Valve 302 stainless steel	Same as Predicate.
Plug, Dye Carrier W/blue Dye Porous Hydrophilic Polyethylene	Plug, Dye Carrier W/blue Dye Porous Hydrophilic Polyethylene	Same as Predicate.
Seal, Manual Vent Valve	Seal, Manual Vent Valve	Same as Predicate.
Ball, 1/2" white polypropylene homopolymer resin	Ball, 1/2" white polypropylene homopolymer resin	Same as Predicate.
Stopper, Tethered Kraton, color: gray	Stopper, Tethered Kraton, color: gray	Same as Predicate.
Drain Body/ Insert/ Back Acrylonitrile butadiene styrene (ABS), White	Drain Body/ Insert/ Back Acrylonitrile butadiene styrene (ABS), White	Same as Predicate.
Drain Cover (Front) Acrylonitrile butadiene styrene (ABS) clear	Drain Cover (Front) Cryo, Cryotlite	Same as Predicate with the exception of a change to material from Cryo, Cryotlite to Acrylonitrile butadiene styrene (ABS) clear

Device Component	PREDICATES: K043140 K043582	Comparison
Tubing Set, Auto Connect (A/C),69	Tubing Set, Auto Connect (A/C),80	Same as Predicate with the exception of a change in tubing length.
Sub Assembly Stopcock Suction Line Low-Density Polyethylene (LDPE).	Sub Assembly Stopcock Suction Line 302 stainless steel spring	The strain relief was changed from a 302 stainless steel spring to a Low-Density Polyethylene (LDPE).
Strain Relief, Patient Tube 6 Low-Density Polyethylene (LDPE)	Strain Relief, Patient Tube 6 302 stainless steel spring	The strain relief was changed from 302 stainless steel spring to a Low-Density Polyethylene (LDPE).
Ink Jet Printing	Silk Screen Printing Ink	Same as Predicate with the exception of a change from Silk Screen printing to Inkjet printing.
Tape, 1/2 Smooth Crepe Color: beige	Tape, 1/2 Smooth Crepe Color: beige	Same as Predicate.
Shipper, Corrugated	Shipper, Corrugated	Same as Predicate.
Label, Blank, Color Stripe, Rub. Red Transprint	Label, Blank, Color Stripe, Rub. Red Transprint	Same as Predicate with the exception of a change to transprint specification.
Instruction For Use (IFU) 40 pound offset	Instruction For Use (IFU) 50 pound offset	Same as Predicate with the exception of change to 40 pound offset.
DEHP Label Label, Blank, 6.5 X 3.75	Label not present in Predicate device	DEHP label added to device .
Iconic IFU Label,Flat,Blank,WT,6.5X4.625	Not present in Predicate device	The addition of an Iconic IFU.
Pouch, Nylon/Tyvek	Bag, Breather	The change did not impact the products ability to meet sterile barrier, presentation into a sterile field, sterilization of the finished device, or packaging and handling requirements.

Non-clinical tests:

The Auto transfusion (ATS) Chest Drains comply with the voluntary standards identified in section 9 of this submission. Atrium Medical's development process required that the following activities be completed during the development of the current configuration of the Ocean Water Seal, Oasis Dry Suction Water Seal and Express Dry Seal Chest Drains.

- specification review
- performance testing
- biocompatibility testing
- sterility testing
- stability testing
- design validation

Clinical tests:

There were no clinical studies of the modified device.

The Auto transfusion (ATS) Chest Drain products are designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users. The risks associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. The clinical evaluation of the product is sufficient to demonstrate both clinical safety and performance of the Auto transfusion (ATS) Chest Drains based on the articles reviewed, and from the low complaint rates and reportable events over the last 5 years. Post-market experience indicates that complications rates in clinical use constitute risks commensurate with the state of the art as indicated by the clinical evaluation.

Conclusion:

The Ocean Water Seal, Oasis Dry Suction Water Seal and Express Dry Seal Chest Drains are similar to the predicate devices in the intended use and the fundamental scientific technology of the device.

The design verification and validation testing established that the Ocean Water Seal, Oasis Dry Suction Water Seal and Express Dry Seal Chest Drains are safe and effective and performs as well as the predicate devices.

Based upon the information submitted in this Traditional 510(k) premarket notification, Ocean Water Seal, Oasis Dry Suction Water Seal and Express Dry Seal Chest Drains are substantially equivalent to the currently marketed Express Chest Drain and Oasis Chest Drain (K043140) and Ocean Water Seal Chest Drain (K043582).