K103042

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510(k) Summary of Safety and Effectiveness

APR 15 2011

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

Date Prepared:

August 09, 2010

Submitter's Information: 21 CFR 807.92(a)(1)

ATMOS Inc.
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Contact Person:
Katrin Georges
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	ATMOS S 201 Thorax and ATMOS E 201 Thorax
Common Name:	Powered suction pump
Classification Name:	PUMP, PORTABLE, SUCTION UNIT (AC-POWERED OR BATTERY) 878.4780, Class II
Product Code:	BTA

Predicate Devices: 21 CFR 807. 92(a)(3)

510(k) Number	K080212
Device Name	Medela THOPAZ
Applicant	Medela AG Medical Equipment Laettichstrasse 4b 6341 Baar Switzerland
Regulation Number	878.4780
Classification Product Code	BTA
Decision Date	07/23/2008
Decision	Substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery

510(k) Number	K043582
Device Name	Ocean Chest Drain
Applicant	Atrium Medical Corporation 5 Wentworth Dr. Hudson; NH 03051
Regulation Number	880.6740
Classification Product Code	KDQ
Decision Date	01/21/2005
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital

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Device Description: 21 CFR 807 92(a)(4)

The ATMOS S 201 Thorax and ATMOS E 201 Thorax drainage suction units are devices for mobile thoracic drainage. The devices are intended for **short-time (<30 days)** application on human beings. They are portable, mains independent and have an electronic monitoring system with optical and acoustic status display. The products are used in unsterile condition, except of the hose set and the collection container, which are sterile single-use products. Any trocars and catheters may be used which their manufacturers have intended for use in thoracic drainage. The ATMOS S 201 and the ATMOS E 201 Thorax are not intended for use in emergency medicine.

Indications for Use: 21 CFR 807 92(a)(5)

The ATMOS E 201 Thorax and the ATMOS S 201 Thorax are indicated for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious material from a patient's respiratory support system after surgery.
The general indication of the ATMOS S 201 Thorax and the ATMOS E 201 Thorax is thoracic drainage.

Technological Characteristics: 21 CFR 807 92(a)(6)

Thoracic drainage pumps as the Medela THOPAZ and the ATMOS E 201 Thorax and ATMOS S 201 Thorax consist of the same functional components. Those functional components are a vacuum source, realized by a pump for both the predicate and the subject devices. The vacuum can be pre-adjusted and is regulated by a software routine. The target value and the actual value is displayed and recorded for direct monitoring of the patient as well as later progress analysis. To achieve mobility the devices are equipped with a rechargeable battery.

The secretion is collected in a sterile container. Containers for thoracic drainage as the one of the Medela THOPAZ are equipped with a bacterial filter that prevents the entry of bacteria and secretion into the interior of the device. An additional function of Thoracic drainage containers may be a water seal as realized in the Ocean Chest Drain and the ATMOS S 201 Thorax and ATMOS E 201 Thorax container.

The ATMOS S 201 Thorax and the ATMOS E 201 Thorax devices are substantially equivalent to other legally marketed devices in the United States and functions in a manner similar and is intended for the same use as the predicate devices.

Brief summary of Non-clinical Tests and Results

The ATMOS S 201 Thorax and ATMOS E 201 Thorax devices have been designed and tested to applicable safety standards and do not raise any new issues of safety, efficacy, or performance of the product.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) for the ATMOS S 201 Thorax and ATMOS E 201 Thorax devices contains adequate information and data to enable FDA to determine substantial equivalence to the predicate devices. The device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ATMOS Inc.
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle, North Carolina 27709

APR 15 2011

Re: K103042
Trade/Device Name: ATMOS E 201 Thorax and the ATMOS S 2 Thorax
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: April 07, 2011
Received: April 08, 2011

Dear Mr. Rongero:

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. 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103042

Device Name: ATMOS E 201 Thorax and the ATMOS S 201 Thorax

Indications for Use:

The ATMOS E 201 Thorax and the ATMOS S 201 Thorax are indicated for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious material from a patient's respiratory support system after surgery. The general indication of the ATMOS S 201 Thorax and the ATMOS E 201 Thorax is thoracic drainage.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) _____

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103042