510(k) Summary of Safety and Effectiveness

FEB 27 2009

K090445

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

Date Prepared:

July 7, 2008

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

Mr. Marco Schlegel, President
ATMOS Inc.
3717 Huckleberry Road
Allentown, PA 18104
Tel: 610.351.7221
Fax: 610.351.6527
Email: MSchlegel@atmosmed.de

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	ATMOS C361/C451 Suction Pump™
Common Name:	Powered suction pump
Classification Name:	Pump, Portable, Aspiration (Manual or Powered) 878.4780, Class II
Product Code:	BTA

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

510(k) Number	K042943
Device Name	NOUVAG AG - VACUSON 40 AND VACUSON 60
Applicant	NOUVAG AG Reusswehrstrasse 1 Gebenstorf, SZ 5412
Regulation Number	878.4780
Classification Product Code	BTA
Decision Date	12/17/2004
Decision	substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery

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

The ATMOS C361/C451 device is an AC/DC-powered surgical suction unit. With a direct docking and direct docking disposable system, hose connection errors are not possible. There is only one connection for the hose to the patient. The connection from the jar to the pump is integrated in the container lid.

The ATMOS C361/C451 is centered on a silent diaphragm-type pump which generates a vacuum inside the collection jar, allowing secretions to be withdrawn and collected. Using a vacuum regulator and the vacuum-gauge, the target vacuum and airflow rate can be adjusted.

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

510(k) Summary of Safety and Effectiveness

The ATMOS C361/C451 Suction Pump™ device is intended for aspiration and collection of secretions, body fluids and tissue from wounds during surgery or at the patient's bedside.

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

ATMOS C361/C451 Suction Pump™ device are substantially equivalent to other legally marketed devices in the United States. The C361/C451 functions in a manner similar and are intended for the same use as the predicate.

Brief summary of Non-clinical Tests and Results

The ATMOS C361/C451 Suction Pump™ device have been designed and tested to applicable safety standards. The C361/C451 Suction Pump does 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 C361/C451 Suction Pump™ device contains adequate information and data to enable FDA to determine substantial equivalence to the predicate device. 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
9200 Corporate Boulevard
Rockville MD 20850

ATMOS, Inc.
% TUV Rheinland of North America, Inc.
Tamas Borsai
12 Commerce Road
Newton, Connecticut 06470

FEB 27 2009

Re: K090445
Trade/Device Name: ATMOS C361/C451 Suction Pump™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: February 20, 2009
Received: February 20, 2009

Dear Tamas Borsai:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Daniel Krane

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090445

Device Name: ATMOS C361/C451 Suction Pump™

Indications for Use:

The ATMOS C361/C451 Suction Pump™ device is intended for aspiration and collection of secretions, body fluids and tissue from wounds during surgery or at the patient's bedside.

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 General, Restorative, and Neurological Devices

510(k) Number K090445