5. 510(k) Summary K113542

Date: August 6, 2011

Contact:

Salter Labs
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Arvin, CA 93203

Michael Shoup
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Trade Name: Salter Lab Bubble Humidifier (High Flow)

Common Name: Bubble Humidifier (High Flow) Model #7900

Classification Name: Respiratory gas humidifier

Classification: 21 CFR 868.5450 Respiratory gas humidifier, Class II

Product Code: BTT

Predicate Devices:

Predicate 510(k)	Device Name	Intended Use	Clearance Date	Company
K991484	Air*Life*® Bubble Humidifier (Model 002006)	Humidifiers are defined as a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient.	May 13, 1999	CareFusion (cleared as Allegiance)
K041963	American Bantex Humidifier Bottle, 6 PSI (Model B9001)	The American Bantex Humidifier is intended for use with Oxygen Concentrators in a patients home, physicians office or hospital/institutional environment. The humidifier increases the moisture content of the airstream gases for administration to the patient.	Oct. 20, 2004	American Bantex Corporation

Device Description:

The Salter Labs Bubble Humidifier (High Flow) is an empty, disposable, non-sterile device that is intended to humidify breathing gas prior to delivery to a patient. The Salter Labs Bubble Humidifier (High Flow) is provided with a 6 PSI safety valve and can operate within flow rates of 6 to 15 LPM. The device is used with various breathing gas sources (i.e., oxygen concentrators, gas cylinders and wall outlets) and provides connection for delivery of humidified breathing gas via face masks and cannulas, and use of optional oxygen tubing and water traps.

The device is made of a humidifier bottle which is used to hold water during use, a lid which seals the humidifier bottle and houses the different interface connectors, an audible pressure relief mechanism to notify the user of a downstream occlusion and a diffuser located inside the humidifier bottle that is designed to uniformly disperse the gas throughout the water. The 360° diffuser ports also provide quiet operation and minimize system backpressure. Both the bottle and lid are constructed to be easy to grip and reduce the chance of cross threading. The jar is permanently marked with minimum/maximum water levels.

Intended Use/Indication For Use:

The bubble humidifier is a device that is intended to add moisture to breathing gases for administration to a patient.

The bubble humidifier is indicated for use with oxygen concentrators or gas sources in homecare, hospital, extended care facilities and hospice environments. The bubble humidifier is a non-sterile device indicated for single-patient usage. The device is indicated for patients who require humidification of high flow supplemental breathing gases.

Technological Characteristics:

Salter Bubble Humidifier (High Flow) is substantially equivalent to the predicate device with regards to design, materials, performance and intended use. The difference is in the operating gas flow rates of 6 to 15 LPM that still produces a humidifier output of at least 10mgH2O/L in accordance with ASTM F1690 (Clause 49.1).

Feature/Performance	Salter Labs	American Bantex	CareFusion (Allegiance) Air*Life*®
Model #	7900	B9001	2006
Method of Humidification	Gas bubbles through the diffuser submerged in a user-filled, water reservoir/bottle and enters the patient breathing gas circuit	Same	Same
Gas Flow Range	6 - 10 LPM Concentrator, 6 - 15 LPM Wall Source	Not Specified	Not Specified
Pressure Relief Value	6 PSI	6 PSI	6 PSI
Audible Notification of Occlusion	Yes	Yes	Yes
Materials of Construction	ABS PVC PP Brass	ABS PVC PP Brass	High Impact PS PP Brass
This product is not made with natural rubber latex	Yes	Not Specified	Label states "Latex Free"
Bottle Capacity	350 ml	Not Specified	370 ml
Used with Oxygen Concentrators, Gas Cylinders and Wall Outlets	Yes	Yes	Not Specified
Complies with applicable clauses of ASTM F1690-96 (2004) and ISO 10993-1: 2009 (Biocompatibility)	Yes	Not Specified, no declaration of conformity to this standard	Not Specified, no declaration of conformity to this standard

Assessment of Non-Clinical Testing

Non-clinical testing of the Salter Bubble Humidifier (High Flow) has been performed against requirements for performance, physical attributes, environmental conditions, materials and safety, and to provide objective evidence that the device's intended use is met. As applicable to the requirements, testing was performed in accordance with ISO

10993, "Biological Evaluation of Medical Devices" for biocompatibility and ASTM F1690-96 (Reapproved 2004), "Standard Specification for Humidifiers for Medical Use-Part 1: General Requirements for Active Humidification Systems" for safety and performance. All acceptance criteria from testing were met.

Conclusion:

The Salter Bubble Humidifier (High Flow) has been verified and validated against design requirements, user needs and intended uses. Based on this testing and the comparison of design, materials, performance and intended use, the Salter Bubble Humidifier (High Flow) raises no new questions concerning safety and effectiveness, and is thus substantially equivalent to the predicate devices.

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

Salter Labs, Arvin Facility
C/O Mr. Casey Conry
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

FEB 10 2012

Re: K113542
Trade/Device Name: Salter Lab Bubble Humidifier (High Flow)
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: January 25, 2012
Received: January 26, 2012

Dear Mr. Conry:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): New 510(k)

Device Name: Salter Lab Bubble Humidifier (High Flow)

Indications for Use: The bubble humidifier is a device that is intended to add moisture to breathing gases for administration to a patient.

The bubble humidifier is indicated for use with oxygen concentrators or gas sources in homecare, hospital, extended care facilities and hospice environments. The bubble humidifier is a non-sterile device indicated for single-patient usage. The device is indicated for patients who require humidification of high flow supplemental breathing gases.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 113542