DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 21, 2017

Salter Labs
Mara Caler
Regulatory Affairs
2365 Camino Vida Roble
Carlsbad, California 92011

Re: K161719
Trade/Device Name: Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: September 14, 2017
Received: September 18, 2017

Dear Mara Caler:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161719

Device Name
Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve

Indications for Use *(Describe)*

The bubble humidifier is intended to add moisture to breathing gases for administration to patients >1 month in homecare, hospital, extended care and hospice.

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.

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.

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510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of substantial equivalence information is provided:

510 (k) Summary

A. Submitter:

Salter Labs
2365 Camino Vida Robles
Carlsbad, CA 92011
Telephone: 760-795-7100
Fax: 760-683-6797

Contact Person: Mara Caler
Regulatory Affairs

Date Prepared: 14 Sept 2017

B. Device Names:

Trade Name	Common Name	Classification Name	Product Code
Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve.	Respiratory gas humidifier	Respiratory gas humidifier	BTT

Regulation Number: 868.5450
Classification: II
Classification Panel: Anaesthesiology (73)

C. Predicate Devices:

This submission demonstrates substantial equivalence to the predicate device:
K113542, Salter Labs Bubble Humidifier

D. Device Descriptions

The Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410 mbars) safety valve is an empty, disposable, non-sterile, not made with natural rubber latex, device intended to

humidify breathing gas prior to delivery to a patient. The Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve is provided with a 6 pounds per square inch (PSI) safety valve and can operate within flow rates of 6 to 15 liters per minute (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 or cannulas, and use of optional oxygen tubing and water traps (face masks, 21 CFR 868.5580; nasal cannulas, 21 CFR 868.5340; oxygen tubing, 21 CFR 868.5860 and water traps, 21 CFR 868.5995 are 510(k) exempt).

This device is a passive device and is not a cascade humidifier, is not heated and is not prefilled.

The device is made of a humidifier bottle which is used to hold water during use, a lid which seals the humidifier bottle, an audible pressure relief mechanism to notify the user of a downstream occlusion and a diffuser located at the end of a PVC diffuser tube inside the humidifier bottle. The diffusor is designed to uniformly disperse the gas throughout the water. Both the bottle and lid are constructed to be easy to grip and reduce the chance of cross threading. The bottle is permanently marked with "minimum/maximum" water levels. The lid is marked with minimum source pressure, flow ranges and pressure value of the safety valve.

E. Indications for Use:

The bubble humidifier is intended to add moisture to breathing gases for administration to patients >1 month in homecare, hospital, extended care and hospice.

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.

E.1: Usage

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.

E.2: Comparison of intended use to the predicate device and separate it from the Indications for Use Statement.

The predicate device is indicated for any patient population requiring humidification of high flow supplemental breathing gases. There are no excluded patient populations. For clarity, a more detailed description of the patient population is defined in the indications for use statement. This device is intended for the same intended population, including patients >1 month in homecare, hospital, extended care and hospice environments.

F. Substantial Equivalence:

Comparison of Technological Characteristics with the Predicate Device

Specification	Predicate: Salter Labs Bubble Humidifier (High Flow)	Test device: Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve	Changes
Device Use & General Characteristics			
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 a non-sterile device indicated for single-patient usage. The device is indicated for patients who require humidification of high flow supplemental breathing gases.	The bubble humidifier is intended to add moisture to breathing gases for administration to patients >1 month in homecare, hospital, extended care and hospice. 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.	The patient population and the use environment has been defined
Target Patient Population	The device is indicated for patients who require humidification of high flow supplemental breathing gases.	The device is indicated for patients >1 month who require humidification of high flow supplemental breathing gases.	The patient population has been defined
Intended use	To humidify breathing gases	To humidify breathing gases	Unchanged
Environment of use	For use in homecare, hospital, acute care facilities, extended care facilities and hospice environments.	For use in homecare, hospital, acute care facilities, extended care facilities and hospice environments.	Unchanged
Use	Single patient use	Single patient use	Unchanged
Supplied as	Non-sterile	Non-sterile	Unchanged
Principal of Operation/ Mechanisms of Action	The bubble humidifier is indicated for use with oxygen concentrators or gas sources to humidify (add water to) the oxygen	The bubble humidifier is indicated for use with oxygen concentrators or gas sources to humidify (add water to) the oxygen	Unchanged
Technology	Air is channelled through a	Air is channelled through a	Unchanged

Specification	Predicate: Salter Labs Bubble Humidifier (High Flow)	Test device: Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve	Changes
Device Use & General Characteristics			
	water-containing bottle. The air then becomes humidified before exiting to the patient	water-containing bottle. The air then becomes humidified before exiting to the patient	
Flow rate	6-15 liters per minute	6-15 liters per minute	Unchanged
Pop-off safety valve	At 6 PSI	At 6 PSI	Unchanged
Power Source	None – this is a passive device	None – this is a passive device	Unchanged
Prescription Use / Over-The-Counter Use	Prescription Devices	Prescription Devices	Unchanged
Sterile / Non-Sterile	Non-Sterile	Non-Sterile	Unchanged
Use	Single patient use	Single patient use	Unchanged
Required preparations prior to use	None	None	Unchanged
Manufacturing Process of Device from Material	Molded (bottle, lid) Extruded (diffuser tube)	Molded (bottle, lid) Extruded (diffuser tube)	Unchanged
Patient-Contact Components	Device does not touch the patient.	Device does not touch the patient.	Unchanged
Labeling	Instructions for Use are unchanged except for the removal of the DEHP symbol.	Instructions for Use are unchanged except for the removal of the DEHP symbol.	SE
Environmental Limitations	Storage temperature: -40 ^{o} C (-40 ^{o}F) to +60 ^{o} C (140 ^{o}F)	Storage temperature: -40 ^{o} C (-40 ^{o}F) to +60 ^{o} C (140 ^{o}F)	Unchanged
Materials			
K113542	PVC (DEHP)	PVC (DOTP)	SE
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant	Unchanged

Similarities and Differences:

Similarities:
The similarities between the Salter Labs Bubble Humidifier and the modified Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve are:

Design: The exact same design is used; there are no changes to the Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve except the materials used in the line/diffusor.

- Both are passive, non-heated, non-powered humidifier bottles. There is no external energy source.
- Both are in-line between the air source and patient circuit (nasal cannula)
- Both are intended for single-patient use.
- Both are supplied non-sterile
- Both use identical pop-off safety valve (6 PSI) made from identical material (brass)
- Both have identical dimensions.

	Parameter (inch)	Comparison to predicate
Bottle		
• Length	5.12	No change
• Diameter (base)	2.75	No change
• Diameter (top)	2.84	No change
Lid		
• Height	2.26	No change
• Diameter	3.08	No change
Tubing		
• Length	5.50	No change
• Diameter	0.29	No change
Diffusor		
• Length	0.51	No change
• Diameter (Base)	0.40	No change
• Diameter (Top)	0.33	No change

- Both have identical performance characteristics
  - Flow rate: 6-15 LPM
  - 6 PSA (410 mbars) for pop-off safety valve

Materials
- Both use identical materials: polyethylene bottle with a polystyrene lid (except as identified in the "differences" table below).

Energy source

- Both use are non-heated, non-powered in-line humidifier bottles. There is no external energy source.

Differences

The differences between the Salter Labs Bubble Humidifier and the modified Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve is a material modification from PVC (DEHP) to PVC (DOTP). The materials used in the remainder of the device are unchanged.

Features	**Predicate K113542**	**Modified device**	**Performance Testing**
Material Formulation of the diffusor tubing and diffusor (all other materials are unchanged.	PVC, DEHP	PVC, DOTP	Biocompatibility and Performance

Standards

Standards used for this submission:

Standard	Test	Results
ISO 10993-5	Biological Evaluation of Medical Devices Part 5: Tests for in-vitro cytotoxicity	Acceptable
ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.	Acceptable
ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	Acceptable

G. Performance Data

The modified Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve was tested to verify that the bond strength of the new material used for the different tube and diffusor met the pre-defined performance specifications.

The test results demonstrate that the modified Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve is substantially equivalent to the predicate devices. No clinical testing was required for this submission. A cleaning study was performed which verified the cleaning outlined in the instructions for use. A useful life study was performed which verified performance up to 120 cleaning cycles.

H. Conclusions

The Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) safety valve data and test results (bond strength testing) demonstrate that the devices are substantially equivalent to the predicate devices. Based on the performance testing performed on the modified device safety valve and bond strength, Salter Labs Bubble Humidifier (6-15 LPM) with 6 PSI (410mbars) we have demonstrated that the modified device continue to perform substantially equivalent to the predicate devices.