DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-002

August 5, 2015

Salter Labs
Ms. Aurelia Brownridge
Regulatory Associate
2365 Camino Vida Roble
Carlsbad, CA 92011

Re: K143700
Trade/Device Name: CPAP Cannulaide®
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 2, 2015
Received: July 6, 2015

Dear Ms. Brownridge:

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 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. 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 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*

K143700

Device Name

CPAP Cannulaide®

Indications for Use *(Describe)*

CPAP Cannulaide is indicated to aid in securing and positioning the nasal interface for neonates and infants undergoing non-invasive ventilation in an acute care setting.

CPAP Cannulaide is a disposable device and is for single patient use only.

Type of Use *(Select one or both, as applicable)*

XX 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."

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

Submitter: Salter Labs
2365 Camino Vida Roble
Carlsbad, CA 92011
Telephone: (760) 795-7100
Fax: (760)-683-6797

Contact Person: Aurelia Brownridge, Regulatory Associate

Date Summary Prepared: August 4, 2015

Device:

Proprietary Name:	CPAP Cannulaide®
Common Name:	Securement and fixation device
Classification Name:	Noncontinuous Ventilator (IPPB) Accessory
Regulatory Class:	II
Product Code:	BZD
Regulation Number:	21CFR 868.5905

Predicate Device: K100011, headgear accessory as part of Patient Nasal Interface of Fisher & Paykel Bubble CPAP System

Reference: K903539, Salter Labs Model # 1015 (Tender Grip)

Device Description: The CPAP Cannulaide® is a die-cut hydrocolloid-coated polyurethane film with an integral hook strip (i.e., Velcro) to allow for the use of a loop material to help secure a nasal interface for non-invasive ventilation. The Cannulaide® is applied above the lip and over the nose to provide a protective barrier between the nasal cannula and the patient's skin. It is available in multiple sizes that vary the external geometry and nare hole size and spacing to allow for use on neonates and infants. It is a non-sterile, single-patient use, disposable device.

Indications For Use: CPAP Cannulaide® is indicated to aid in securing and positioning the nasal interface for neonates and infants undergoing non-invasive ventilation in an acute care setting.

CPAP Cannulaide® is a disposable device and is for single patient use only.

Patient Population: The intended patient population is neonatal and infant.

Environment of Use: Hospitals. Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU).

Substantial Equivalence Discussion
The CPAP Cannulaide® is viewed as substantially equivalent to the predicate device because:

Indications for Use

- Similar use to predicate, the accessory bonnet and straps of the F&P Infant Interface (K100011); both are intended to aid in securing the nasal interface when non-invasive CPAP is used.
- For CPAP therapy, it is important to protect nasal area from patient interface device. The CPAP Cannulaide® has the same intent as the predicate devices for positioning and securement of the CPAP patient interface device.

Discussion: CPAP Cannulaide® is used in addition to the securement accessory of the predicate K100011 but secures the nasal prongs at the patient's nose and offers a physical barrier between the nasal interface and the septum and the skin.

This difference does not alter the intended use compared to the predicate, thus the CPAP Cannulaide® can be considered substantially equivalent.

Environment of Use

- The environments of use are identical to the predicate accessory bonnet and straps of the F&P Infant Interface (K100011).

Discussion: The environments of use are identical and thus can be considered substantially equivalent.

Patient Population

- Similar patient population to the accessory bonnet and straps of the F&P Infant Interface (K100011).
- Patients who are treated with non-invasive ventilation requiring nasal prongs.

Discussion: Both the proposed device and the predicate have similar patient populations, neonate and infant, and thus can be considered substantially equivalent.

Technology

- The technology of using an adhesive to adhere to the patient's skin and to secure a nasal cannula is identical to the reference device.
- The principles of operation of both the predicate and reference device are for positioning and securement of nasal interfacing devices.

Discussion: The technology of using an adhesive to adhere to a patient's skin and to hold a nasal cannula in place is substantially equivalent to the reference device, Salter Tender Grip (K903539) and in principle to the predicate device, while the predicate accessory bonnet and straps of the F&P Infant interface (K100011) use a bonnet and straps.

Material

- The materials used to adhere to the skin and secure the nasal interface have been evaluated via ISO 10993-1 testing as well as Extractable and Leachable testing. The materials were found to be biocompatible and have limited reactivity.
- Same level of biocompatibility for intact skin surface devices, using established standards testing.

Discussion: Testing has been conducted on the materials to address biocompatibility per ISO 10993-1. Biocompatibility results support that the materials do not raise any new safety or efficacy concerns compared to the predicate accessory bonnet and straps of the F&P Infant Interface (K100011).

Differences:

Indications for Use

- The CPAP Cannulaide® is used in addition to the standard nasal interface securement accessory. It is designed to secure the nasal interface near the nose while the standard nasal interface securement accessories do not secure near the nose but along the head.
- The combination of these two securement means support each other to improve the securement and positioning of the nasal interface.

Materials:

- CPAP Cannulaide® uses a hydrocolloid barrier to protect the patient's skin which is recommended for these types of applications. While different than that of the predicate F&P accessory bonnet and straps, the materials have been evaluated via ISO 10993. Based on the biocompatibility results, the materials do not raise any new safety or efficacy concerns compared to the predicate accessory bonnet and straps of the F&P Infant Interface.

Non-clinical Performance Testing:

Material Biocompatibility
G95-1 and ISO 10993-1 classify the proposed device as Surface Contact, Skin, Prolonged Duration (> 24 h to 30 d)

The following tests were performed:

- Cytotoxicity
- Sensitization
- Irritation
- Additionally, exhaustive Extractable and Leachable testing including a risk-based assessment was also performed

Performance Testing
We performed a number of tests to demonstrate that the changes do not raise any new safety or efficacy concerns, and support the claims. These tests included:

- Comparative securement (peel)
- Comparative sealing of nasal prongs
- Seal maintenance
- Age / Shelf-life for 2 years
- Performance in high humidity conditions

Comparison Table:

Device	CPAP Cannulaide®	Predicate K100011 F&P Healthcare FlexiTrunk Infant Interface
Intended Use	CPAP Cannulaide® is a single use, non-sterile device that provides a barrier to protect the nasal area skin on neonates and infants undergoing noninvasive ventilation, while aiding in positioning and securement, and enabling sealing of the nasal interface to the patient. CPAP Cannulaide is intended to be used by trained clinicians.	The F&P Bubble CPAP infant interface device is indicated to provide CPAP to spontaneously breathing neonates and infants who require breathing support. It includes a nasal interface and means of securing this, both of which are accessories to the CPAP device.
Indications for Use	CPAP Cannulaide® is indicated to aid in securing and positioning the nasal interface for neonates and infants undergoing non-invasive ventilation in an acute care setting. CPAP Cannulaide® is a disposable device and is for single patient use only.	F&P Bubble CPAP Patient Nasal Interface is indicated to provide CPAP to spontaneously breathing neonates and infants who require breathing support.
Warnings	Do not use to secure endotracheal tubes. Do not use with low or high flow oxygen nasal cannulas. Do not use with nasal CPAP masks. Excess condensation in the CPAP circuit and interface may interfere with the CPAP Cannulaide adhesion properties. Follow your facility's procedure for managing circuit condensation.	Not for use with non-spontaneously breathing infants, infants not requiring CPAP support, gas flows over 15L/min and in non-hospital environments.
Principal of Operation / Mechanism of Action	The CPAP Cannulaide® adheres to a patient's skin and allows the nasal cannula to be secured to the CPAP Cannulaide® keeping the cannula in place. Utilizes hydrocolloid adhesive and hook and loop strips to attach to the patient and secure the cannula. It is used in addition to the standard securement devices provided with the CPAP nasal interfaces.	A securing and anchoring accessory, bonnet and straps, are an accessory to the nasal interface that consists of prongs, FlexiTrunk, and bonnet with straps to secure and keep the cannula in place.
Environment of Use	Hospitals, Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU).	Hospitals, clinical environments such as the NICU and PICU.

Device	**CPAP Cannulaide®**	**Predicate K100011 F&P Healthcare FlexiTrunk Infant Interface**
Disposable / Reusable	Single patient use, disposable.	Single patient use.
Material Between Patient and Device	Adhesive – Hypoallergenic for skin-sensitive individuals.	Cotton / Nylon Blend, Nylon / Neoprene Laminate, Nylon / Polyurethane Laminate Silicone.
Patient Population	Neonates and infants.	Premature and full term neonates up to a weight of 10 kg.
Key Technological Feature		
Hydrocolloid	The hydrocolloid helps to provide a protective barrier between the CPAP interface and the infant's skin.	The Bubble CPAP interface is commonly taped to the skin.
Adhesive Strip for Securing Device	Yes	Yes
Placement of Prongs	Helps to maintain placement of nasal prongs in the nares.	Recommended that placement of prongs is in the center of nares.
Seal	The nasal opening of the CPAP Cannulaide® provides a secondary seal around the nasal prongs. The nasal prongs provide the primary seal.	The F&P Nasal Prongs provide the fit and seal in the nares themselves.
Skin Barrier	The CPAP Cannulaide® acts as a protective barrier between the nasal interface and the patient's skin.	The F&P Nasal Interface rests directly on the skin.
Placement	The CPAP Cannulaide® helps to maintain a space between the base of the nasal prongs and the septum.	The placement of the Patient Nasal Interface by F&P is recommended to be at least 2 mm from the septum, but there is no physical barrier to prevent direct contact with the septum.
Securement	The hook and loop strips on the CPAP Cannulaide® helps to prevent movement of the interface to maintain proper positioning in addition to the standard securement device supplied with the nasal interface.	The bonnet and side straps help to maintain proper positioning of nasal interface but there is no direct securement of the prongs at the nares.

Substantial Equivalence Conclusion
The CPAP Cannulaide® based upon testing has been found to be substantially equivalent to the predicate accessory bonnet and straps of the F&P Infant Interface (K100011).

The differences between the proposed device and the predicate do not raise new questions of safety or efficacy.