DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

March 11, 2016

Salter Labs
Margaret Caler
Regulatory Associate
2365 Camino Vida Robles
Carlsbad, California 92011

Re: K151506
Trade/Device Name: NOP Demand Nasal Oxygen Cannula, Models 4804, 4805, 4807, 4824, & 4827 and NOP Modified Demand Nasal Oxygen Cannula, Models 4904, 4905, & 4907
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NFB
Dated: February 5, 2016
Received: February 11, 2016

Dear Ms. 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 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,
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Infection Control and Dental Devices
Office of Device Evaluation
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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)*
K151506

Device Name
NOP Demand Nasal Oxygen Cannula, Models 4804, 4805, 4807, 4824, & 4827 and NOP Modified Demand Nasal Oxygen Cannula, Models 4904, 4905, & 4907.

Indications for Use *(Describe)*
The intended use is to deliver oxygen to the patient nasally, controlled by a demand system

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Section 9.0: 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), a the following summary 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
Director, Regulatory Affairs

Date Prepared: 11 March 2016

**B. Device Names:**

| Trade Name | Common Name |
|---|---|
| NOP Demand Nasal Oxygen Cannula models: 4804, 4805, 4807, 4824, & 4827. | NOP Demand Nasal Oxygen Cannula |
| NOP Modified Demand Nasal Oxygen Cannula models: 4904, 4905, & 4907. | NOP Modified Demand Nasal Oxygen Cannula |

**Classification Name:** Conserver, Oxygen
**Product Code:** NFB
**Regulation Number:** 868.5905
**Classification:** II
**Classification Panel:** Anaesthesiology

**C. Predicate Devices:**

This submission demonstrates substantial equivalence to the predicate devices:

K890298, Demand Nasal Oxygen Cannula

K892407, Modified Demand Nasal Oxygen Cannula

## D. Device Descriptions

The demand cannula is a special cannula designed to give adult and pediatric users of dual port oxygen conservation delivery system all the comfort and conveniences of a Salter-Style® cannula. Unique dual tubing delivers oxygen on demand through one tube while inspiratory / expiratory effort is also sensed through the other tube. Meets dual port device manufacturers' specifications.

## E. Indications for Use

The intended use is to delivery oxygen to patient nasally, controlled by a demand system.

## F. Comparison of Technological Characteristics with the Predicate Device

The proposed NOP Demand Nasal Oxygen Cannula and Modified NOP Demand Nasal Oxygen Cannula is substantially equivalent to the predicate device listed above in that the the indications for use, the intended use, and fundamental scientific technology remain unchanged.

The differences between the NOP Demand Nasal Oxygen Cannula and Modified NOP Demand Nasal Oxygen Cannula and the predicate device are:

| Features | Predícate Demand Nasal Oxygen Cannula | NOP Demand Oxygen Cannula | Performance Testing |
|---|---|---|---|
| Material Formulation | PVC, DIDP | PVC, DINCH | Biocompatibility and Performance |
| | PVC, DEHP | PVC, DOTP | |

## G. Performance Data

The NOP Demand Nasal Oxygen Cannula and Modified NOP Demand Nasal Oxygen Cannula were tested to verify that the new material bond and performance characteristics of flow rate, back pressure, and tubing bond strength did not impact the strength or performa nce of the modified demand devices after the material change. Statistical methods were used to determine, the minimum required sample size was 29 to support a 95% confidence level at 91% reliability.

The test results demonstrate that the NOP Demand Nasal Oxygen Cannula and Modified NOP Demand Nasal Oxygen Cannula is substantially equivalent to the predicate devices.

The tests performed are summarized below:

| Criteria | Results | Comments |
|---|---|---|
| Shall not have a back pressure that exceeds 3 psi at a maximum flow rate in ambient of 5°C, 20°C, and 40°C | The NOP Demand/Modified Demand Nasal Oxygen Cannula met the objective back pressure requirements | Maximum back pressure was found to be less than 2 psi. |
| The bonded components of the set will have a bond strength that is ≥ 2 lbs. when pulled at a rate of 5 inches per minute. | The NOP Demand/Modified Demand Nasal Oxygen Cannula passed all bond strength requirements. All test samples measured above the bond interface tensile load limit. | The worst case cannula sample was able to achieve over 2 times the minimum allowable value. |
| The cannula shall withstand storage and transport temperatures. A high temperature limit of 50°C and a low temperature limit of -29°C. | The NOP Demand/Modified Demand Nasal Oxygen Cannula met the above performance criteria after storage and transport environmental conditioning. | N/A |

The NOP Demand Nasal Oxygen Cannula and Modified NOP Demand Nasal Oxygen Cannula meet established Salter Labs performance specifications.

**H. Clinical / Non-Clinical**

The following biocompatibility testing was performed. The materials passed all parameters:

- Irritation
- Sensitization ·
- Cytotoxicity
- Particulate
- Volatile organic compounds

**I.** Conclusions

The NOP Modified Demand and NOP Demand Nasal Oxygen Cannula data and test results demonstrate that the devices are substantially equivalent to the predicate devices