DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 10, 2016

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

Re: K151421
Trade/Device Name: Nasal CO2 Sample Line; O2 Delivery / CO2 Sampling Nasal Cannula; Oral / Nasal CO2 Sampling Cannula; O2 Delivery with Oral / Nasal CO2 Sampling Cannula; Divided O2 Delivery / CO2 Sampling Nasal Cannula and Sample Lines
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 1, 2016
Received: March 3, 2016

Dear Margaret 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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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)*
K151421

Device Name
Nasal CO2 Sample Line; O2 Delivery / CO2 Sampling Nasal Cannula; Oral / Nasal CO2 Sampling Cannula; O2 Delivery with Oral / Nasal CO2 Sampling Cannula; Divided O2 Delivery / CO2 Sampling Nasal Cannula and Sample Lines

Indications for Use *(Describe)*

The Nasal CO2 Sample Line is intended to be used to sample exhaled gas.

The O2 Delivery / CO2 Sampling Nasal Cannula is intended to be used where low flow oxygen is administered and exhaled gas is monitored.

The Oral / Nasal CO2 Sampling Cannula is intended to be used where exhaled gas is monitored.

The O2 Delivery with Oral / Nasal CO2 Sampling Cannula is intended to be used where low flow oxygen is administered and exhaled gas is monitored.

The Divided O2 Delivery / CO2 Sampling Nasal Cannula is intended to be used where low flow oxygen is administered and exhaled gas is monitored.

The Sample Lines are intended to be used where exhaled gas is monitored.

Environment of use – hospital, sub-acute, and pre-hospital settings.

Patient population – Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 safety and effectiveness 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

B. Contact Person:

Mara Caler
Director, Regulatory Affairs

C. Date Prepared:

09 March 2016

D. Device Names:

Trade Name:	Nasal CO2 Sample Line; O2 Delivery / CO2 Sampling Nasal Cannula; Oral / Nasal CO2 Sampling Cannula; O2 Delivery with Oral / Nasal CO2 Sampling Cannula; Divided O2 Delivery / CO2 Sampling Nasal Cannula and Sample Lines
Classification Name:	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Product Code:	CCK
Regulation Number:	868.1400
Classification:	II
Classification Panel:	Anesthesiology (73)

Trade Name	**Common Name**
Nasal CO_2 Sample Line	Nasal CO_2 Sample Line
O_2 Delivery / CO_2 Sampling Nasal Cannula	Oxygen delivery / CO_2 Sampling Nasal Cannula
Oral / Nasal CO_2 Sampling Cannula	Oral / Nasal CO_2 Sampling Cannula
O_2 Delivery with Oral / Nasal CO_2 Sampling Cannula	Oxygen Delivery-Oral /Nasal CO_2 Sampling
Divided O_2 Delivery / CO_2 Sampling Nasal Cannula	Infusion / Aspiration Cannula
Sample Lines	Sample Lines

Predicate Devices:

This submission demonstrates substantial equivalence to the predicate devices: K863703, Nasal CO_2 Sample Line
K863883, O_2 Delivery / CO_2 Sampling Nasal Cannula
K864199, Oral / Nasal CO_2 Sampling Cannula
K864902, O_2 Delivery with Oral / Nasal CO_2 Sampling Cannula K892406, Divided O_2 Delivery / CO_2 Sampling Nasal Cannula K894350, Sample Lines
The proposed devices that correspond to these predicates have identical names and are listed in the table below.

E. Device Descriptions

Device Name	Device Description
Nasal CO_2 Sample Line	The device is a non-sterile, disposable, single patient use cannula that allows sampling of patients exhaled gases.
O_2 Delivery / CO_2 Sampling Nasal Cannula	The device is a non-sterile, disposable, single patient use cannula that provides supplemental oxygen while sampling patients exhaled gases.
Oral / Nasal CO2 Sampling Cannula	The device is a non-sterile, disposable, single patient use cannula that allows sampling of patients exhaled gases from both the nares and orally.
O2 Delivery with Oral / Nasal CO2 Sampling Cannula	The device is a non-sterile, disposable, single patient use cannula that provides supplemental oxygen while sampling patients exhaled gases, using two nasal inserts. One insert samples the CO_2 while the other delivers the oxygen. The Cannula includes Salter Eyes®, an aperature in the nasal prong intended to minimize occlusions and Oral-Trac, a method of sampling orally exhaled gases. The ETCO2 Cannula with oxygen delivery can also be purchased with the Oral-Trac® feature to allow oral (mouth) ETCO2 sampling.
Divided O2 Delivery / CO2 Sampling Nasal Cannula	The Salter Labs ETCO2 Cannula provides O_2 delivery in one nostril and samples exhaled CO_2 from the other nostril using a divided nasal insert.
Sample Lines	The Salter Labs ETCO2 Tubing consists of flexible extruded plastic tubes with connectors on each end, with differing configurations.

F. Indications for Use

The Intended/Indications for Use Statement is described below:

Intended / Indications for Use
The Nasal CO_2 Sample Line is intended to be used to sample exhaled gas.
The O_2 Delivery / CO_2 Sampling Nasal Cannula is intended to be used where low flow oxygen is administered and exhaled gas is monitored.
The Oral / Nasal CO_2 Sampling Cannula is intended to be used where exhaled gas is monitored.
The O_2 Delivery with Oral / Nasal CO_2 Sampling Cannula is intended to be used where low flow oxygen is administered and exhaled gas is monitored.
The Divided O_2 Delivery / CO_2 Sampling Nasal Cannula is intended to be used where low flow oxygen is administered and exhaled gas is monitored.
The Sample Lines are intended to be used where exhaled gas is monitored.

Environment of use – hospital, sub-acute, and pre-hospital settings
Patient population – Patients requiring supplemental oxygen and / or expired gas monitoring, adult to pediatrics.

G. Comparison of Technological Characteristics with the Predicate Device

The proposed Modified ETCO2 Devices are substantially equivalent to the predicate devices listed above in that the indications for use, the intended use, device dimensions, device specifications and fundamental scientific technology remain unchanged.

The differences between the Modified ETCO2 Devices and predicate devices are:

Features	**Predícate ETCO2 Devices**	**Modified ETCO2 Devices**	**Performance Testing**
Material Formulation	PVC, DIDP	PVC, DINCH	Biocompatibility
	PVC, DEHP	PVC, DOTP & DINCH	Biocompatibility
Shelf life	None	3 years	Performance testing after simulated 3 year aging

H. Performance Data

The proposed device was tested to verify that the new material did not affect the bond and performance characteristics of flow rate, back pressure. The test results demonstrate that the device is substantially equivalent to the predicate devices

Performance Testing Summary

Criteria	Predicate specifications	Modified devices	Comments
Back pressure (flow rates):	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.	Maximum back pressure was found to be less than 2 psi.	The modified devices passed all specifications
Bond Strength (tensile strength):	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 bond strength test achieved over 2 times the minimum allowable value.	The modified devices passed all specifications
Device dimensions:	Unchanged.	Unchanged.	The modified devices use the same molds and are unchanged from the predicate devices

The modified ETCO2 Devices meet established Salter Labs performance specifications.

I. Clinical / Non-Clinical

No clinical testing was required for this submission.

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

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

J. Conclusions

ETCO2 device data and test results demonstrate that the device is substantially equivalent to the predicate devices.