K131410

JAN 13 2014

**510(k) Summary**

**Date:** **January 8, 2014**

**Trade Name:** **CO2/O2 Nasal Cannula**

**Common Name:** Oxygen Delivery, Carbon Dioxide Sampling Nasal Cannula

**Classification Name:** Carbon Dioxide Gas Analyzer

**Regulation:** Class II per 21CFR 868.1400

**Product Code:** **CCK**

**Sponsor:** Southmedic Inc.
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Canada
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**LEAGALLY MARKETED PREDICATE DEVICES**

This premarket notification will demonstrate that Southmedic's CO2/O2 Sampling Nasal Cannula is substantially equivalent to the devices listed below:

- Salter Labs #4706 $CO_2/O_2$ Nasal Cannula (K892406)
- Hudson RCI BiFlow 1850 (K961150)
- UnoMedical/Hospitak 368E (K915228)

**DEVICE DESCRIPTION**

Southmedic's CO2/O2 Nasal Cannula incorporates sampling nares that channel expired carbon dioxide to a capnograph. A port located between the two nares is used to deliver oxygen to the patient as needed from an oxygen source. Its unique design delivers O2 to both the nose and mouth area. This device when in use involves surface contact to the patient's intact skin. There

is also gas pathway contact between patient and tubing/nasal cannula. Contact is considered limited exposure (up to 24 hours).

**INTENDED USE**

This device is intended to provide a means for sampling end tidal carbon dioxide with the option to deliver supplemental $O_2$ therapy to patients for up to 24 hours.

**TECHNOLOGICAL CHARACTERISTICS**

Southmedic's $CO_2/O_2$ Nasal Cannula and the predicate devices have similar technological characteristics. Specifically Southmedic's $CO_2/O_2$ Nasal Cannula and the predicate devices are all designed to draw expired end-tidal $CO_2$ from the patient through the nasal cannula and tubing to a capnograph, and administer medical grade USP $O_2$ to patients from an oxygen supply.

Southmedic's $CO_2/O_2$ Nasal Cannula's cannula has been designed with slight differences from the predicate devices. All predicate cannulae have two separate systems built into the part to allow for the delivery of oxygen and sampling of end-tidal carbon dioxide. Each predicate takes a different approach. Exhaled carbon dioxide is collected through the nasal prongs and a single port was created central to the nasal prongs for $O_2$ delivery in Southmedic's model. Modification to the outer portion helps direct $O_2$ down towards the mouth as well as the nose.

**SUBSTANTIAL EQUIVALENCE SUMMARY**

| **Characteristic** | **Southmedic's $CO_2$ Sampling Nasal Cannula** | **Salter Labs #4706 CO2/O2 Nasal Cannula** | **Hudson RCI BiFlow 1850** | **UnoMedical/Hospitak 368E** |
|---|---|---|---|---|
| 510(k) | K131410 | K892406 | K961150 | K915228 |
| Intended Use | This device is intended to provide a means for sampling $ETCO_2$ with the option to deliver supplemental $O_2$ therapy to patients. | Same | Same | Same |
| Prescription | Yes | Yes | Yes | Yes |
| Technological Characteristics | Provides a means to deliver exhaled $CO_2$ to a capnograph via | Same | Same | Same |

| Characteristic | Southmedic's $CO_2$ Sampling Nasal Cannula | Salter Labs #4706 CO2/O2 Nasal Cannula | Hudson RCI BiFlow 1850 | UnoMedical/Hospitak 368E |
|---|---|---|---|---|
| | tubing, provides a means to deliver continuous USP grade medicinal $O_2$ as necessary. | | | |
| Design | Collects $CO_2$ from nasal prongs and delivers $O_2$ though a single port between nasal prongs | Delivers oxygen from one nasal prong and samples $CO_2$ from the other. | Delivers oxygen and samples $CO_2$ from both nasal prongs. | Same as Southmedic's, however, $O_2$ delivery through two ports rather than one. |
| Material | Phthalate free PVC<br><br>Not made with natural rubber latex. | PVC containing Phthalates<br><br>Not made with natural rubber latex. | PVC containing Phthalates<br><br>Not made with natural rubber latex. | PVC containing Phthalates<br><br>Not made with natural rubber latex. |
| Energy Used or Delivered | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Manufacturing Process | Injection molding, extrusion, assembly | Injection molding, extrusion, assembly | Injection molding, extrusion, assembly | Injection molding, extrusion, assembly |
| Performance | Same | Same | Same | Same |
| Labelling | Same | Same | Same | Same |

**TESTING**

In order to support the specific safety of Southmedic's CO2/O2 Nasal Cannula, as well as confirm the suitability of the materials used in the manufacture of this product, extensive biocompatibility studies were contracted to an independent laboratory. The following table summarizes the biocompatibility testing conducted by Nelson Labs:

| **Biocompatibility Testing** | |
|---|---|
| **Test/Method:** | **Agar Overlay – Test for Cytotoxicity** |
| **Objective:** | To determine the cytotoxicity of diffusible components from materials. |
| **Acceptance Criteria** | The United States Pharmacopeia & National Formulary (USP 87) states that the test article meets criteria if the reactivity grade is not greater than 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states the achievement of a numerical grade greater than 2 is considered a cytotoxic effect. |
| **Results:** | Three samples were investigated obtaining an average score of 1. Results were compared to both positive and negative controls (average scores of 4 and 0 respectively). |
| **Discussion:** | Southmedic's CO2/O2 Nasal Cannula is composed of materials that do not have a cytotoxic effect. This supports the safety of the device as well as the suitability of the materials used in its production. |
| **Test/Method:** | **ISO 10993 Part 10 Guinea Pig Buehler Sensitization Test** |
| **Acceptance/Evaluation Criteria** | Test results were based on incidence and severity of the sensitization reaction. Incidence was defined as the percentage of animals exhibiting a sensitization reaction at each observation time point (24 and 48 hours) post challenge. Severity was calculated by dividing the sum of the scores of one (1) or greater in the test group generally indicated sensitization, provided grades of less than one (1) were observed in the control animals. If severity of one (1) or greater was noted on the controls, then the reaction of the test animals exceeded the most severe control reaction to be considered due to sensitization. In the final analysis of data consideration was given to overall patterns, intensity, duration and character of reactions of the test as compared to the control animal. |
| **Results:** | No sensitization reaction was observed in either the control or test group. |
| **Discussion** | Southmedic's CO2/O2 Nasal Cannula is composed of materials that do not have a sensitization effect. This supports the safety of the device as well as the suitability of the materials used in its production. |

<table>
<tr><td>Test/Method:</td><td>ISO 10993 Part 10 – Primary Skin Irritation Test in Rabbits</td></tr>
<tr><td>Acceptance/Evaluation Criteria:</td><td>After the 72 hour scoring, all erythema plus edema scores generated during the 24±2, 48±2, and 72±2 hour observations were totaled separately for each test sample and control for each animal. The resulting totals for each animal were divided by 6 (two tests/observation site, three time points) to determine separate test article and control primary irritation scores for each animal. The primary irritation index is characterized by the number (score) and description (response category) given in below:
<table>
<tr><th>Response Category</th><th>Primary Irritation Index (PII)</th></tr>
<tr><td>Negligible</td><td>>0 to 0.4</td></tr>
<tr><td>Slight</td><td>0.5 to 1.9</td></tr>
<tr><td>Moderate</td><td>2 to 4.9</td></tr>
<tr><td>Severe</td><td>5 to 8</td></tr>
</table></td></tr>
<tr><td>Results:</td><td>The test subject received a Primary Irritation Index Score of 0 in all areas.</td></tr>
<tr><td>Discussion:</td><td>Since no skin irritation was observed in the test subjects, this test demonstrates that Southmedic's CO2/O2 Nasal Cannula is composed of materials that are a non-irritant to skin. This supports the safety of the device as well as the suitability of the materials used in its production.</td></tr>
</table>

Risk evaluation performed by Southmedic determined that because of the well characterized safe and effective use of nasal cannulas for oxygen delivery and end tidal $CO_2$ sampling, animal or clinical testing were not necessary to support this application. In order to confirm effectiveness of Southmedic's CO2/O2 Nasal Cannula for its intended use, a comparative performance bench test against predicate devices was contracted from an independent laboratory. The following table summarizes the performance testing conducted by Piper Laboratory:

| Study Attribute | Description |
|---|---|
| **Test subjects** | Southmedic's CO2/O2 Nasal Cannula was tested and results compared against predicate devices (see above) |
| **Objective** | To measure the end tidal CO2 values of four oxygen delivering nasal cannulae under simulated patient conditions |
| **Acceptance Criteria** | End tidal CO2 values for Southmedic Nasal Cannula shall not be statistically different, or shall vary less from the true end tidal CO2 value than the predicate products |
| **Apparatus** | Harvard Respiratory pump and mannequin head to simulate patient head. Nasal cannula connected to oxygen supply line, CO2 sensing line and CO2 detector (capnograph) |

| | |
|---|---|
| **Simulated Respiratory Settings** | 1. Adult, Respiratory Rate 8, Tidal Volume 800<br>2. Adult, Respiratory Rate 16, Tidal Volume 600<br>3. Pediatric, Respiratory Rate 30, Tidal Volume 300<br>All conditions had I:E ratio of 1:1 (inspiration:expiration) |
| **Deviations** | No deviations were noted during the study. All equipment met predetermined operation and calibration testing before and after testing |
| **Oxygen delivery for study** | Source flows of 0, 1, 3, and 5 liters per minute for each setting was used. The system was allowed at least 3 minutes with oxygen deliver prior to sampling CO2 to allow the system to equilibrate. |
| **Measurements** | Each test was sampled three times at each combination of settings for a total of 144 tests ( 4 samples x 4 tests per sample x 3 respiratory settings x 4 oxygen flow rate settings = 144 tests total) |
| **Results** | The end-tidal CO2 values for the Southmedic CO2/O2 Nasal Cannula was not statistically different, or varied less from the true end tidal CO2 value than predicate products.<br>A comparison of variances of the end tidal CO2 measurements from the actual value for all four devices indicates that the Southmedic nasal cannula has the least variance from true value when compared to the three predicate devices within 95% confidence intervals. |
| **Discussion** | The Southmedic CO2/O2 Nasal Cannula met the predetermined acceptance criteria of the test.<br>Both Southmedic's CO2/O2 Nasal Cannula and predicate devices are intended to provide a means for sampling $ETCO_2$ with the option to deliver supplemental $O_2$ therapy to patients. This performance test demonstrated that Southmedic's CO2/O2 Nasal Cannula performs equally to, or better than, the predicate devices in measuring end tidal CO2. This supports the substantial equivalence of Southmedic's CO2/O2 Nasal Cannula to the predicate products. |

## CONCLUSIONS

In summary, Southmedic's CO2/O2 Nasal Cannula path through the 510(k) regulatory analysis is as follows:

- The Southmedic CO2/O2 Nasal Cannula and the predicate devices are all intended for use as a means for sampling ETCO2 with the option to deliver supplemental O2 therapy to patients.
- The Southmedic CO2/O2 Nasal Cannula has similar key technological characteristics as the predicate devices. All three are manufactured by extrusion, injection molding, and assembly. Designs are based on the same principle of one tube providing oxygen from a source and the other delivering expired CO2 to a capnograph.
- In order to verify the safety of the materials used in the manufacture of Southmedic's CO2/O2 Nasal Cannula, extensive biocompatibility testing was conducted. The testing demonstrated that materials used have no cytotoxic effect. The testing also confirmed

that the materials used are a non-irritant and do not have a sensitization effect. These results help support the safety of Southmedic's CO2/O2 Nasal Cannula

- The use of nasal cannulas for sampling CO2 and delivering oxygen is well established in the medical community. In order to address any difference between Southmedic's CO2/O2 Nasal Cannula and the predicate devices in their design, additional studies were performed. In order to demonstrate the effectiveness of the new design, a comparative bench test was conducted on Southmedic's behalf. The results demonstrated that Southmedic's CO2/O2 Nasal Cannula varied less or equal to the true values when compared to the predicate device. This supports the effectiveness of the device.

Therefore, Southmedic's CO2/O2 Nasal Cannula meets the criteria for substantial equivalence to Salter Lab's CO2/O2 Nasal Cannula, Hudson RCI Biflow Cannula, and the UnoMedical/Hospitak Nasal Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2014

Southmedic Incorporated
Ms. Tish Anger
Vice President of Quality and Regulatory Assurance
50 Alliance Blvd.
Barrie, Ontario
Canada L4M 5K3

Re: K131410
Trade/Device Name: CO2/O2 Nasal Cannula
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: December 12, 2013
Received: December 13, 2013

Dear Ms. Anger:

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.

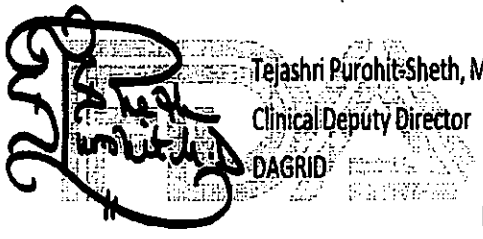
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (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

Erin I. Keith, M.S.
Acting Director
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

| | |
|---|---|
| **510(k) Number:** | K131410 |
| **Device Name:** | $CO_2/O_2$ Nasal Cannula |
| **Intended Use:** | This device is intended to provide a means for sampling end tidal carbon dioxide with the option to deliver supplemental $O_2$ therapy to patients for up to 24 hours. |

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan J. Patel -S
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