K012395

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Oridion

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3.0 510(k) Summary

Product name
Proprietary: MAC-Line O_2/CO_2 Nasal Cannula sample line
Common: Nasal Cannula Gas sampling line for capnograph with integrated Oxygen Administration means for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation.

Establishment registration number
Establishment registration number: 8044004

Establishment Address:
ORIDION MEDICAL 1987 LTD.
HAR HOTZVIM SCIENCE BASED INDUSTRIAL PARK
POB 45025
91450 JERUSALEM, ISRAEL

Device Listing Fda Form 2892:
A 733250

Product classification
The MAC-Line O_2/CO_2 Nasal Cannula sample line is classified as Class II according to 21CFR868.1400 (73CCK)

INTENDED USE:

The intended use of the MAC-Line O_2/CO_2 Nasal Cannula sample line is to conduct a sample of the adult/pediatric subject's breathing from the subject, via a nasal cannula, to a gas measurement device (capnograph) while simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation.

DEVICE DESCRIPTION

The common product name for this device is Nasal Cannula Gas sampling line for capnograph with integrated Oxygen Administration means for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation. The complete device is a combined device consisting of two devices, as described below, integrated to simultaneously perform the function of both devices

The CO_2 gas sampling nasal cannula is used with a capnograph (carbon dioxide analyzer 21CFR 868.1400). There is a nasal cannula at one end of the device for connecting to the patient's nose, a Microstream sample tube with a Male or Female Luer lock on the other end for connecting to the capnograph. The CO_2 Cannula is identical to the Oridion CO_2 Nasal Cannula K980325.

Attached and integrated with the CO_2 nasal cannula is another device for simultaneously administering supplemental oxygen projected near the nose and mouth for inhalation. The O_2 cannula has a tube with a standard O_2 connector bushing on the end for connecting to a normal O_2 supply. The O_2 device is classified as class I according to 21CFR868.5340.

PREDICATE DEVICE

There are three predicate devices:

- The Oridion O_2/CO_2 predicate device is the Microstream O_2/CO_2 Nasal Cannula Filterline.
- The Adult predicate device is the Hospitak disposable CO_2 Gas sampling/Oxygen delivery Cannula K915228.
- The Pediatric predicate device is the Salter Laboratories Model 4701 CO_2 Gas sampling/Oxygen delivery Cannula.

SUBSTANTIAL EQUIVALENCE:

The MAC-Line O_2/CO_2 Nasal Cannula sample line is a combination device that combines a CO_2 sampling nasal cannula with a O_2 supply nasal cannula.

- The MAC-Line O_2/CO_2 Nasal Cannula sample line is essentially equivalent to the Hospitak disposable CO_2 Gas sampling/Oxygen delivery Cannula K915228.
- The Oridion Pediatric MAC-Line O2/CO2 Nasal Cannula sample line is essentially equivalent to the Salter Laboratories Model 4701 CO2 Gas sampling/Oxygen delivery Cannula

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BIOCOMPATIBILITY

Requirements

The parts of this product which comes into contact with the patient's nose have been tested for biocompatibility. The methods used for testing were:

1. Physicochemical tests, plastics, complete (Aqueous exfract)
2. Cytotoxicity study using the ISO elution method (Extract)
3. ISO Sensitization test in 15 Guinea Pigs, per extract (Maximization method) Saline Extract, Cottonseed Extract
4. ISO Acute Intracutaneous Reactive study in three rabbits, Saline Extract, Cottonseed Extract.
5. Detailed reports are found in Appendix A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Mr. Sanford Brown
Regulatory Affairs Manager
Oridion Medical 1987 Ltd.
P.O. Box 45025
Jerusalem 91450
Israel

Re: K012395
Mac-Line O_2/CO_2 Nasal Cannula Sample Line
Regulation Number: 868.1400
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: July 23, 2001
Received: July 27, 2001

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oridion

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5.0 INDICATIONS FOR USE FORM

510(k) Number (if known): K012395

Device Name:
MAC-Line O_2/CO_2 Nasal Cannula sample line

Indications For Use:
The MAC-Line O_2/CO_2 Nasal Cannula sample line device is used whenever the physician needs to measure the CO_2 in an adult or pediatric non intubated subject's breathing via a nasal cannula while simultaneously administering supplemental oxygen near the nose and mouth for inhalation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012395

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