K094012

7. 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

(This section is not confidential)

MAY 12 2010

DATE THIS SUMMARY WAS PREPARED

December 15th, 2009

SUBMITTER'S NAME AND ESTABLISHMENT ADDRESS:

Oridion Capnography Inc.
160 Gould Street
Needham, MA 02494

ESTABLISHMENT REGISTRATION NUMBER

3003941644

CONTACT PERSON:

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DEVICE INFORMATION

Trade Name: Capnostream20
Common Name: Two Parameter Bedside Monitor
Classification Name: Capnograph/Pulse Oximeter
Regulation Number:
868.1400, Carbon Dioxide Analyzer (Classification CCK)
870.2700 Pulse Oximeter (Classification DQA)
Device Listing Number: D001115.

PREDICATE DEVICE

Capnostream20 with the microMediCO2 CO2 board is substantially equivalent to the following commercially available device:

Manufacturer	Device	510(k)No.	Clearance Date
Oridion 1987 Medical Ltd	Capnostream20	K082268	February 9th, 2009

DEVICE DESCRIPTION

The Capnostream20 bedside monitor is a two parameter monitor consisting of a CO2 capnography module and a pulse oximetry module implemented in a host device. The host device displays parameters received from the respective modules and generates alarms when preset alarm thresholds are crossed. The device is classified as CCK Class II according to 21 CFR § 868.1400 - Carbon Dioxide Analyzer with DQA 21 CFR § 870.2700 Pulse Oximeter listed as an additional or alternate classification.

This device has two modules that are classified as follows:

- 21 CFR 868.1400, Carbon Dioxide Analyzer (Classification CCK)
- 21 CFR 870.2700 Pulse Oximeter (Classification DQA)

Each module is controlled by dedicated software that is an integral part of the respective module.

INTENDED USE

The Capnostream20 combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers the continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra-hospital transport and home environments.

The Capnostream20 monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the

patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring

COMPARISON TO PREDICATE DEVICE

The Capnostream20 with the micromediCO2 CO2 module is substantially equivalent to the predicate Capnostream20 with the minimediCO2 CO2 module.

The new device meets the safety and performance standards met by the predicate device.

The functional features and the intended use of the Capnostream20 with the new CO2 module are substantially equivalent to the predicate device. No significant changes were made to the monitor hardware or software specifications to support the integration of the new module. Slight mechanical changes were made to the monitor to accommodate the smaller dimensions of the new module. The micromediCO2 module is smaller in size than the miniMediCO2 module, in order to facilitate integration inside other OEM monitors, and provides enhanced processing and memory capacity, to support software applications for future development. The module provides the following inputs to the host monitor:

FiCO2, EtCO2 numeric, EtCO2 waveform, Respiratory Rate, IPI (Integrated Pulmonary Index), and continuous CO2 numeric and waveform.

The micromediCO2 includes a smaller lamp, a new solenoid, broader use of molded parts to improve production quality, increased processing power, reduced power consumption and improved flow regulation.

The module software provides full backward compatibility with the miniMedicO2 and supports RS232 or USB communication with the host monitor.

A hazard analysis was carried out on the module and on the Capnostream20 monitor with the new module. This hazard analysis concluded that any residual risks were judged as acceptable when weighed against the intended benefits of use of the system. Verification and validation of the new module as a standalone and when integrated in the monitor were successfully completed.

Attribute	**Capnostream20 Bedside Monitor with microMediCO2CO2 module**	**Predicate Device- Capnostream20 Bedside Monitor K082268**
Indications for use	The indications for use are identical to the indications for use in the predicate device	The Capnostream20 combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers the continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2 and pulse rate). It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital transport and home environments.
Target population	It is intended for use with neonatal, pediatric, and adult patients.	It is intended for use with neonatal, pediatric, and adult patients.
Design	Identical to the Capnostream20 described in K082268 with the exception of the introduction of the micromediCO2 CO2 module	See K082268
Where Used	It is to be used by physicians, nurses and other trained health care providers in critical care patient settings, such as anesthesiology, intensive care medicine, neonatal intensive care and other health care areas.	It is to be used by physicians, nurses and other trained health care providers in critical care patient settings, such as anesthesiology, intensive care medicine, neonatal intensive care and other health care areas.
Performance Standards	ISO 21647 ISO 9919	ISO 21647 ISO 9919
Safety Standards	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC 60601-1-8 UL 60601-1 ISO 14971	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC 60601-1-8 UL 60601-1 ISO 14971
Biocompatibility	There are no issues of biocompatibility for this device and no biocompatibility testing was done.	There are no issues of biocompatibility for this device and no biocompatibility testing was done.
Sterility	This device does not require sterilization and is shipped marked non-sterile.	This device does not require sterilization and is shipped marked non-sterile.

CONCLUSION

Capnostream20 with the micromediCO2 CO2 module does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed device. Therefore, the device is substantially equivalent to the predicate device with respect to safety, effectiveness, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY 12 2010

Ms. Rachel Weissbrod
Director of Regulatory Affairs
Oridion Capnography, Incorporated
160 Gould Street
Needham, Massachusetts 02494

Re: K094012
Trade/Device Name: Capnostream20 with Micromedico2 Module
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: April 13, 2010
Received: April 15, 2010

Dear Ms. Weissbrod:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Statement of Indications for Use

TWO PARAMETER CAPNOSTREAM MONITOR

(This document is not confidential)

Indications for Use

December 15th, 2009

510(k) Number (if known) K094012

Device Name: Capnostream 20

Indications for Use:

The Capnostream20 combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers the continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital transport and home environments.

The Capnostream20 monitor provides the clinician with an integrated pulmonary index (IPI). The IPI is based on four parameters provided by the monitor: end tidal carbon dioxide, respiration rate, oxygen saturation and pulse rate. The IPI is a single index of an adult or pediatric patient's ventilatory status displayed on a scale of 1 - 10, where 10 indicates optimal pulmonary status. IPI monitoring displays a single value that represents the patient's pulmonary parameters and alerts clinicians to changes in the patient's pulmonary status.

The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.

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

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K094012