K082268

2. 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)

FEB - 9 2009

DATE THIS SUMMARY WAS PREPARED

August 5, 2008

SUBMITTER'S NAME AND ESTABLISHMENT ADDRESS:

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ESTABLISHMENT REGISTRATION NUMBER

3003941644

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DEVICE INFORMATION

Trade Name: Capnostream 20 with Integrated Pulmonary Index
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: B051971

PREDICATE DEVICE

Capnostream 20 with the Integrated Pulmonary Index (IPI) software is substantially equivalent to the following commercially available device:

Manufacturer	Device	510(k)No.	Clearance Date
Oridion 1987 Medical Ltd	Capnostream 20	K072295	October 11th, 2007

DEVICE DESCRIPTION

The Capnostream 20 bedside monitor is a two parameter monitor consisting of a miniMediCO$_2$ 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. Each module provides parameters to the host software (the Capnostream 20 device software) which then controls the display of the received parameter values and creates alarms when the values cross the preset thresholds. The miniMediCO$_2$ capnography module software presented in this submission includes the ability to receive SpO$_2$ and pulse rate values from a pulse oximetry module and to calculate an integrated pulmonary index (IPI) which provides a simple and clear single parameter representation of the patient's ventilatory status. The IPI, is an integer value ranging from 1-10 based on end tidal CO$_2$, respiration rate, SpO$_2$ (oxygen saturation of arterial hemoglobin) and pulse rate. The calculated IPI is then provided to a host device (the Capnostream 20 device in the case of this submission). The host displays the index value on the screen

alongside the four parameters presented on the predicate device. The IPI feature is not intended for use in the monitoring of children aged less than one year or neonates and the feature is disabled when neonatal mode is selected by the user. However, the monitor itself may continue to be used, in a manner that is identical to the predicate device in all respects, for all patient populations.

The MiniMediCO2 module software is designed to enable the index to be calculated by accepting SpO2 and heart rate values supplied at the required rate (once a second) by any type of pulse oximetry module implemented in a host device. The miniMediCO2 module with IPI software may be implemented in any other pulse oximetry enabled host monitor after making the required changes to the host software to allow provision of SpO2 and pulse rate values to the module and display of the IPI by the host. The host will continue to display the four reference parameters and any other parameters provided by the monitor with the IPI as an addition.

INTENDED USE

The Capnostream 20 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 Capnostream 20 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 Capnostream 20 with IPI is equivalent to the predicate Capnostream 20 (miniMediCO2 software version 2.31) with the exception of the software changes to the miniMediCO2 capnography module and the changes to the Capnostream 20 host software.

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

Software testing was performed to validate the performance of the new software and its substantial equivalence to the predicate device. A clinical evaluation was performed to ensure that the modified device meets user requirements. A safety and effectiveness evaluation was performed to demonstrate that the IPI identified all instances in which clinical intervention was required and alerted the practitioner to these changes. The functional features and the intended use of Capnostream 20 with IPI are substantially equivalent to the predicate device.

A hazard analysis was carried out on the module with the IPI functionality and on the Capnostream 20 host monitor displaying the IPI values. This hazard analysis concluded that any residual risks were judged as acceptable when weighed against the intended benefits of use of the system.

Attribute	**Capnostream 20 Bedside Monitor with MiniMediCO$_2$ EtCO$_2$ module with IPI software (version 2.51)**	**Predicate Device- Capnostream 20 Bedside Monitor K072295**
Indications for use	The indications for use are identical to the indications for use in the predicate device with the addition of the following: The Capnostream 20 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,	The Capnostream 20 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

	oxygen saturation and heart 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.	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 Capnostream 20 described in K072295 with the exception of the software changes in both the EtCO2 module and host monitor described in this submission	See K072295
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(2001) IEC 60601-1-8 UL 60601-1 ISO 14971	IEC/EN 60601-1 IEC/EN 60601-1-2(2001) 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

Capnostream 20 with the IPI functionality 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
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2009

Ms. Rachel Weissbrod
Director of Regulatory Affairs
Oridion Capnography, Incorporated
c/o Oridion Medical 1987 Limited
Har Hotzvim Science Park, POB 45025
Jerusalem
Israel 91450

Re: K082268
Trade/Device Name: Capnostream20
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK
Dated: January 9, 2009
Received: January 27, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Statement of Indications for Use

TWO PARAMETER CAPNOSTREAM 20 MONITOR WITH INTEGRATED PULMONARY INDEX (IPI)

(This document is not confidential)

Indications for Use

August 15, 2008

510(k) Number (if known):__K082268__

Device Name: Capnostream 20

Indications for Use:

The Capnostream 20 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 Capnostream 20 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: K082268