K072295

CONFIDENTIAL

4. 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

OCT 11 2007

(This document is not confidential)

DATE THIS SUMMARY WAS PREPARED

August 15, 2007

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: Capnostream$_{20}$ with A^2 software

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 new miniMediCO$_2$ module adaptive averaging (A^2) software is substantially equivalent to the following commercially available device:

Manufacturer	Device	510(k)No.	Clearance Date
Oridion 1987 Medical Ltd	Capnostream$_{20}$	K060065	May 4th, 2006

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.

This device has two modules that are classified as follows:

- 21 CFR 868.1400, Carbon Dioxide Analyzer (Classification CCK)
- 21 CFR870.2700 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 an adaptive averaging algorithm defined as the A^2 Algorithm for calculating the respiration rate from the CO2 waveform introduced in software version 2.31 of the miniMediCO$_2$ capnography module software. The calculated respiration rate parameter is then provided to the host (the Capnostream$_{20}$ device software). The host makes no modification to the values received from the module. The host triggers an alarm when the respiration rate high or respiration rate low thresholds have been crossed. The algorithm employed in the respiration rate calculation reduces false positive alarms by filtering out noise and instantaneous fluctuations without missing true alarms that may indicate a clinically significant change to respiration rate. By

employing the adaptive averaging algorithm, the respiration rate accurately reflects the patient's condition and significantly reduces the generation of nuisance alarms by the host.

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.

COMPARISON TO PREDICATE DEVICE

The $Capnostream_{20}$ with adaptive averaging (A^2) software (miniMediCO2 software version 2.31) is identical to the predicate $Capnostream_{20}$ (miniMediCO2 software version 2.20) with the exception of the algorithm changes. No changes to the host ($Capnostream_{20}$) software were made to support the new module algorithms and no significant hardware changes have been made to the device.

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

Test data are provided to validate the performance of the software and its substantial equivalence to the predicate device. The functional features and the intended use of $Capnostream_{20}$ with adaptive averaging software are substantially equivalent to the predicate device.

A hazard analysis was carried out on the module with the new algorithms. 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 adaptive averaging (A^2) software (version 2.31)**	**Predicate Device- $Capnostream_{20}$ Bedside Monitor K060065**
Indications for use	The indications for use are identical to the indications for use in the predicate device	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.
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 MiniMediCO$_2$ module in K060065 with the exception of software version change from 2.20 to 2.31	See K060065
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	ISO21647 ISO 9919	ISO21647 ISO 9919
Safety Standards	IEC/EN60601-1 IEC/EN60601-1-2(2001) IEC60601-1-8 UL60601-1 ISO 14971	IEC/EN60601-1 IEC/EN60601-1-2(2001) IEC60601-1-8 UL60601-1 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 adaptive averaging software 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

OCT 11 2007

Oridion Capnography, Incorporated
C/O Ms. Rachel Weissbrod
Director of Regulatory Affairs
Oridion Medical 1987 Limited
Har Hotzvim Science Park
Post Office Box 45025
91450 Jerusalem
ISRAEL

Re: K072295
Trade/Device Name: Capnostream$_{20}$
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK
Dated: September 16, 2007
Received: September 20, 2007

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.

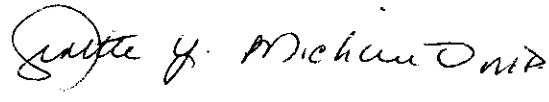
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
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Enclosure

3. Statement of Indications for Use

TWO PARAMETER CAPNOSTREAM20 MONITOR WITH ADAPTIVE AVERAGING SOFTWARE

(This document is not confidential)

Indications for Use

August 15, 2007

510(k) Number (if known) K072295

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.

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: K072295