JUL 19 2012

K112368

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)

DATE THIS SUMMARY WAS PREPARED

July 5, 2012

SUBMITTER'S NAME AND ESTABLISHMENT ADDRESS:

Oridion Medical 1987 Ltd.
7 HaMarpe Street, Har Hotzvim Industrial Park,
Jerusalem, 91450, Israel

ESTABLISHMENT REGISTRATION NUMBER

8044004

CONTACT PERSON:

Dalia Givony, Director of Regulatory Affairs
Oridion Medical 1987 Ltd.
Har Hotzvim Science Based Industrial Park
POB 45025
91450 Jerusalem, Israel
Telephone: +972-2-589 9115
FAX: +972-2-586-6680

DEVICE INFORMATION

Trade Name: Capnostream20p with Smart A/hr & ODI™

Common Name: Two Parameter Bedside Monitor

Classification Name: Capnograph/Pulse Oximeter/Ventilatory Effort Recorder

Regulation Number:

868.1400, Carbon Dioxide Analyzer (Classification CCK)

870.2700 Pulse Oximeter (Classification DQA)

868.2375 Ventilatory Effort Recorder (Classification MNR)

PREDICATE DEVICE

Capnostream20p with Smart A/hr & ODI™ is substantially equivalent to the following commercially available devices:

Manufacturer	Device	510(k) No.	Clearance Date
Oridion 1987 Medical Ltd	Capnostream20p	K101995	January 11, 2011

DEVICE DESCRIPTION

The Capnostream20p bedside monitor is a two parameter monitor consisting of a microMediCO2 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 microMediCO2 module provides the following inputs to the host monitor:

FiCO2, EtCO2 numeric, EtCO2 waveform, Respiratory Rate, IPI (Integrated Pulmonary Index), Continuous CO2 numeric and waveform, Apnea per Hour (A/hr) and Oxygen Desaturation Index (ODI).

The SpO2 module, integrated in the Capnostream20p monitor presented in this submission, provides the following parameters to the host for display: SpO2 (functional oxygen saturation of arterial hemoglobin), pulse rate, SpCO: carboxyhemoglobin saturation in blood (%SpCO), SpMet: methemoglobin saturation in blood (%SpMet), SpHb: total hemoglobin concentration in blood (g/dl SpHb). The SpO2 measurements are also provided to the microMediCO2 module enabling the calculation of the IPI and the ODI.

The host monitor will display this data to the user in numerics via a screen, and will also display the CO_2 waveform and SpO_2 (pleth) waveform or pulse bar graph.

The Apnea per Hour (A/hr) is defined as the number of cessations of breathing of 10 seconds or more that have occurred per hour. The Oxygen Desaturation

Index (ODI) is the number of desaturation events of 4% or more with a return to baseline within 240 seconds or less identified with pulse oximetry (following the AASM definitions)[1]. The values are updated once a minute.

The Smart A/hr & ODI™ feature presented in this submission is intended only for adult patients (age 22 and up) in hospital ICU and general floor environments, whilst the patient is being monitored using capnography and pulse oximetry as part of his medical care. The feature is not available for pediatric, infant and neonatal patients.

INTENDED USE

The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.

The Capnostream®20p 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.

SUBSTANTIAL EQUIVALENCE

The Capnostream20p with Smart A/hr & ODI™ is substantially equivalent to the predicate Capnostream20p with Masimo MX1 SpO2 board.

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 monitor and its substantial equivalence to the predicate device. The functional features and the intended use of Capnostream20p are substantially equivalent to the predicate device.

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

The minor differences between the Capnostream20p with Smart A/hr & ODI™ and its predicate device raise no issue of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate devices 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

Ms. Rachel Weissbrod
Oridion Medical 1987 Limited
7 Hamarpe Street, Har
Hotzvim Industrial Park
Jerusalem, Israel 91450

JUL 19 2012

Re: K112368
Trade/Device Name: Capnostream20p with Smart A/hr & ODI™
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: Class II
Product Code: CCK, DQA, MNR
Dated: July 15, 2012
Received: July 17, 2012

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,

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

Statement of Indications for Use

CAPNOSTREAM®20p with Smart A/hr & ODI™
(This document is not confidential)

July 5th, 2012

510(k) Number (if known) K112368

Device Name: Capnostream20p with Smart A/hr & ODI™

Intended Use/ Indication for Use

The Capnostream®20p combined capnograph/pulse oximeter monitor and its accessories are intended to provide professionally trained health care providers with continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and with continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is also indicated for continuous non-invasive monitoring of carboxyhemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor), methemoglobin saturation (measured by an SpCO/SpMet/SpHb sensor) and total hemoglobin concentration (measured by an SpCO/SpMet/SpHb sensor). It is intended for use with neonatal, pediatric, and adult patients in hospitals, hospital-type facilities, intra-hospital transport and home environments.

The Capnostream®20p 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: K112368