DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 23, 2015

Oridion Medical 1987 Ltd
Ms. Dalia Givony
Regulatory Affairs Manager
7 Hamarpe Street
Jerusalem, Israel 9777407

Re: K150272
Trade/Device Name: Capnostream™ 35 Portable Respiratory Monitor
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, DQA, MNR
Dated: June 11, 2015
Received: June 16, 2015

Dear Ms. Givony:

This letter corrects our substantially equivalent letter of July 17, 2105.

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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Radiological Health

Enclosure

001_Statement Indications for Use

Capnostream™35 Portable Respiratory Monitor
(This document is not confidential)

February 1, 2015

510(k) Number (if known) _____

Device Name: Capnostream™35 Portable Respiratory Monitor

Indications for Use:

Intended Use

The Capnostream™35 is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused.

The Capnostream™35 also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for age 22 and up.

The device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.

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)

510K Summary

This summary is being submitted in accordance with the requirements of 21 CFR 807.92

(*This section is not confidential*)

DATE THIS SUMMARY WAS PREPARED

July 15, 2015

SUBMITTER'S NAME AND ESTABLISHMENT ADDRESS:

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ESTABLISHMENT REGISTRATION NUMBER

8044004

CONTACT PERSON:

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DEVICE INFORMATION

Trade Name: Capnostream™35 Portable Respiratory Monitor; PM35MN

Common Name: Portable Respiratory Monitor

Device Classification Name: analyzer, gas, carbon-dioxide, gaseous-phase

Regulation Number:

868.1400, Carbon Dioxide Analyzer (Classification CCK)
Subsequent product codes:
870.2700 Pulse Oximeter (Classification DQA)
868.2375 Ventilatory Effort Recorder (Classification MNR)

PREDICATE DEVICE

Capnostream™35 is substantially equivalent to the following commercially available devices:

Manufacturer	Device	510(k) No.	Clearance Date
Primary predicate:			
Oridion Medical 1987 Ltd.	Capnostream20p With Smart A/hr & ODI™	K112368	July 19, 2012
Secondary predicate:			
Covidien, LLC	Bedside Respiratory Patient Monitoring System With Respiration Rate Software	K130320	February 4, 2014

DEVICE DESCRIPTION

The Capnostream™35 is a 4-inch color screen portable 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:

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

The SpO2 module integrated in the Capnostream™35 monitor presented in this submission provides SpO2 and Pulse Rate parameters to the host for display.

The SpO2 measurements are also provided to the microMediCO2 module, enabling the calculation of IPI and ODI.

The host monitor will display this data to the user on a screen as numeric values, and will also display the CO2 waveform and SpO2 (pleth) waveform or pulse bar graph.

The device is intended for use in hospitals, hospital-type facilities, and during intra-hospital transport as well as during out-of-hospital Emergency Medical Service applications. The device features IP54 Liquids & Solids ingress protection, 1.25M Shockproof status, sunlight readable display, automatic display brightness, hot swap battery capability and altitude use up to 15000 feet (4572m) for use in out-of-hospital Emergency Medical Service applications.

INTENDED USE

The Capnostream™35 is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused.

The Capnostream™35 also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for patients age 22 and up.

The device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.

COMPARISON TO PREDICATE DEVICE

The Capnostream™35 is substantially equivalent to the following predicate devices:

Attribute	**Primary Predicate Device:** Capnostream20p With Smart A/hr & ODI (K112368)	**Secondary Predicate Device:** Bedside Respiratory Patient Monitoring System With Respiration Rate Software (K130320)	**Subject Device** : Capnostream™35 Portable Respiratory Monitor
Classification	II	II	II
Product Code	CCK DQA MNR	DQA Subsequent code: BZQ	CCK Subsequent code: DQA MNR
Purpose and Function	Continuous non-invasive monitoring of expired and inspired CO2, EtCO2, respiration rate (provided from the Capnograph module), SpO2 and pulse rate	Continues non-invasive monitoring of SpO2, pulse rate and respiratory rate	Same as K112368 (Respiration Rate is derived by Capnography)
Target population	Neonatal, pediatric, and adult patients. A/hr and ODI indication for use is for adult patients age 22 and up. IPI is intended for pediatric and adult patients only.	SpO2, Pulse Rate: Adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused. Respiration Rate: adult patients who are well perfused during no motion	Same as K112368. SpO2, Pulse Rate: same as K130320

		conditions	
Where used	In hospitals, hospital-type facilities, intra-hospital transport and home environments	SpO2, Pulse Rate: In hospitals, hospital-type facilities, and during intra hospital transport. Respiration Rate: hospitals and hospital-type facilities.	In hospitals, hospital-type facilities, intra-hospital transport, out-of-hospital Emergency Medical Service applications that include ground and air transport.
Fundamental Technology	NDIR (CO2) Spectrophotometry and Plethysmography	Spectrophotometry and Plethysmography	Same as K112368
Performance Standards	ISO 21647 ISO 9919	EN 80601-2-61	ISO 80601-2-55 ISO 80601-2-61
Main Safety Standards	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC 60601-1-8 IEC 60601-2-49	EN 60601-1 IEC 60601-1-2 EN 60601-1-4 EN 60601-1-8 EN 60601-1-6	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-8 IEC 60601-2-49 IEC 60601-1-12 IEC 60601-1-6

TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS

The Capnostream™35 features the same technology (NDIR, Spectrophotometry and Plethysmography) as its primary predicate K112368 and the same performance characteristics as its predicates K112368 and K130320. The capnograph module (microMediCO2) integrated in the Capnostream™35 performs as in the predicate K112368 and the SpO2 module integrated in the Capnostream™35 performs as in the predicate K130320. The device was designed to support its use in out-of-hospital Emergency Medical Service applications for which it features IP54 Liquids & Solids ingress protection, 1.25M Shockproof status, sunlight readable display, automatic display brightness, hot swap battery capability and altitude use up to 15000 feet (4572m).

PERFORMANCE TESTING

Non-clinical tests were performed to support the determination of substantial equivalence. Appropriate safety, environmental and performance tests were conducted to ensure that the specifications of the Capnostream™35 were met. The device has successfully undergone performance testing according to ISO 80601-2-55 and ISO 80601-2-61 as well as electrical safety, electromagnetic and environmental testing according to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-2-49, IEC 60601-1-12 and IEC 60601-1-6. Software testing was performed to validate the performance of the new monitor and its substantial equivalence to the predicate devices.

Wireless communication testing was conducted according to FDA guidance document from Aug 13,2013- Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff.

A hazard analysis was carried out on the Capnostream™35 monitor in compliance with ISO 14971:2012. This hazard analysis concluded that any residual risks were judged as acceptable when weighed against the intended benefits of use of the device.

Substantial Equivalence

The Capnostream™35 has the same intended use, technological characteristics and performance as its predicate devices. Compared to its predicate devices, the Capnostream™35 is intended also for out-of-hospital Emergency Medical Service applications. Its functionality in its intended environments was verified.

The Capnostream™35 has successfully undergone performance, electrical safety, electromagnetic, environmental and wireless communication testing to ensure it complies with its performance testing requirements. Testing did not raise any concerns when compared to its predicate devices therefore the subject device is substantially equivalent to its predicate devices.