10.1.3.2. 510(k) Summary of Safety and Effectiveness Information Capnostream$_{20}$ and Capnostream

510(k) Summary of Safety and Effectiveness Information Capnostream$_{20}$ and Capnostream$_{10}$

(This document is not confidential)

DATE THIS SUMMARY WAS PREPARED

March 20, 2006

SUBMITTERS NAME AND ESTABLISHMENT ADDRESS:

Oridion Capnography Inc.

21 Highland Circle

Needham, MA 02494-3038

PRODUCT NAMES

NOTE: This summary statement is for a bundled submission and covers the Capnostream$_{20}$ and Capnostream$_{10}$

Capnostream$_{20}$

Proprietary: Capnostream$_{20}$

Common: Two Parameter Bedside Monitor

Capnostream$_{10}$

Proprietary: Capnostream$_{10}$

Common: One Parameter Bedside Monitor

ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 3003941644

CONTACT PERSON:

Sanford Brown, Regulatory Affairs Director

Oridion Medical 1987 Ltd.

Har Hotzvim Science Based Industrial Park

POB 45025

91450 Jerusalem, Israel

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DEVICE LISTING FDA FORM 2892:

B051971

DEVICE DESCRIPTIONS

❖ Capnostream$_{20}$

The Capnostream$_{20}$ bedside monitor is a two parameter monitor consisting of an $EtCO_2$ MiniMediCO$_2$ module and a MP100 SpO_2 module, displays and alarms.

SUBSTANTIAL EQUIVALENCE INFORMATION

- **CO_2 Module (MiniMediCO$_2$)** used in legally marketed Predicate Devices:
  - ✓ Oridion Polaris 2004, K040011,
  - ✓ CAS Medical Systems, Inc Models 750c-2ms, 750cm-2ms, 750c-Nnl, 750cm with MiniMediCO$_2$-V1 K050844
  - ✓ Larsen & Toubro Limited Star 50 Monitoring System K051608
- **Pulse Oximeter Module,** SpO_2 Module (MP100) used in legally marketed Predicate Devices:
  - ✓ NPB OxiMax Pulse Oximeter System With N-595 Pulse Oximeter, K012891
  - ✓ NPB Oximax N-550, K021090
- **Nurse Call**
  - ✓ NPB OxiMax Pulse Oximeter System With N-595 Pulse Oximeter, K012891
  - ✓ Welch Allyn Atlas Monitor K022084

CLASSIFICATION

Capnostream$_{20}$

73CCK Class II

This device has two modules that are classified as follows:

- 21 CFR 868.1400, carbon dioxide analyzer
- 21 CFR870.2700 Pulse Oximeter

INTENDED USE

The Capnostream$_{20}$ is intended for CO_2 and SpO_2 indications. 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 moves and home environments.

DEVICE DESCRIPTION

The Capnostream$_{20}$ Bedside Monitor is comprised of two modules used in previously FDA cleared devices with the following indications for use, which together are the indications for use for the two parameter bedside monitor:

Capnostream$_{20}$

1. The MiniMediCO$_2$ EtCO$_2$ Module:

Is intended for installation in host devices that: are 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 where non invasive measurement of expired CO_2 and inspired CO_2 are of medical value. It continuously and non invasively measures and monitors carbon dioxide concentration of the expired and inspired breath and respiration rate. This module is designed to be installed in a host device, in this case the two Parameter Bedside Monitor, that is for prescription use only.

2. **The MP100 Oximetry Module**

Is indicated 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 during both no motion and motion conditions and for patients who are either well or poorly perfused. 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. This module is designed to be installed in a host device, in this case the two Parameter Bedside Monitor, that is for prescription use only. .

- **Capnostream$_{10}$**

Capnostream$_{10}$

Proprietary: Capnostream$_{10}$

Common: One Parameter Bedside Monitor

ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 3003941644

CONTACT PERSON:

Sanford Brown, Regulatory Affairs Director

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91450 Jerusalem, Israel

Telephone: +972-2-589-9115

FAX: +972-2-586-6680

DEVICE LISTING FDA FORM 2892:

B051971

DEVICE DESCRIPTION

The Capnostream$_{10}$ bedside monitor is a one parameter monitor consisting of a MP100 EtCO_2 module displays and alarms.

SUBSTANTIAL EQUIVALENCE INFORMATION

- **CO_2 Module (MiniMediCO_2) used in Predicate Devices:**
  - ✓ Oridion Polaris 2004, K040011,
  - ✓ CAS Medical Systems, Inc Models 750c-2ms, 750cm-2ms, 750c-Nnl, 750cm with MiniMediCO_2-V1 K050844
  - ✓ Larsen & Toubro Limited Star 50 Monitoring System K051608

CLASSIFICATION

Capnostream$_{10}$

73CCK Class II

This device is classified as follows:

- 21 CFR 868.1400, carbon dioxide analyzer

INTENDED USE

The Capnostream$_{10}$ is intended for CO_2 indications only. The Capnostream$_{10}$ 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. It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital moves and home environments.

DEVICE DESCRIPTION

The Capnostream$_{10}$ Bedside Monitor contains a MinMediCO$_2$ EtCO$_2$ module used in previously FDA cleared devices with the following indications for use.

The MiniMediCO$_2$ EtCO$_2$ Module:

Is intended for installation in host devices that: are 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 where non invasive measurement of expired CO_2 and inspired CO_2 are of medical value. It continuously and non invasively measure and monitor carbon dioxide concentration of the expired and inspired breath and respiration rate.

This module is designed to be installed in a host device, in this case the one Parameter Bedside Monitor, that is for prescription use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2006

Oridion Capnography, Incorporated
C/O Mr. Stanford Brown
Regulatory Affairs Director
Oridion Medical 1987 Limited
Har Hotzvim Science Based Industrial Park
POB 45025
91450 Jerusalem, Israel

Re: K060065
Trade/Device Name: Capnostream$_{20}$
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 6, 2006
Received: April 7, 2006

Dear Mr. Brown:

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) 276-0120. 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 (301) 443-6597 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
Center for Devices and
Radiological Health

Enclosure

10.1.3.1. Indications for Use

Two Parameter CAPNOSTREAM$_{20}$ Monitor and Single Parameter Capnostream$_{10}$ Monitor

(This document is not confidential)

Indications for Use

March 20, 2006

510(k) Number (if known)___K060065

Device Name: Capnostream$_{20}$

Indications For Use:

The Capnostream$_{20}$ is intended for CO_2 and SpO_2 indications. 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 moves and home environments.

Device Name: Capnostream$_{10}$

Indications For Use:

The Capnostream$_{10}$ is intended for CO_2 indications only. The Capnostream$_{10}$ 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. It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital moves 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 of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K060065