K024300

APR - 3 2003

3. 510(k) Summary of Safety and Effectiveness Information

PRODUCT NAME

Proprietary: MicroCap Plus/NPB-75

Common: Combination Oximeter/Carbon Dioxide Gas Analyzer

ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 8044004

ESTABLISHMENT ADDRESS:

Contact Person: Sanford Brown, Regulatory Affairs Director

Oridion Medical 1987 Ltd.

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DEVICE LISTING FDA FORM 2892:

B051971

DEVICE DESCRIPTION

The Oridion MicroCap Plus/NPB-75 (the device being modified) (K964239) is an integrated instrument that measures end tidal CO_2 ($EtCO_2$) and saturated arterial oxygen (SpO_2). As a derivative of the $EtCO_2$ measurement the devices measure and display the breath rate (BR) and as a derivative of the saturated arterial oxygen measurement the devices measure and display the pulse rate (PR). The capnograph section of both devices function as a carbon dioxide gas analyzer that measures in mmHg, Vol %, or kPa the concentration of CO_2 in a gas mixture to aid in determining the patient's ventilatory status. The pulse oximeter module in both devices measures the oxygenated hemoglobin (HbO_2) and displays the results as a percent of oxygen and as a plethysmographic waveform.

The MP507 pulse oximeter module (Nellcor Puritan Bennett) in the modified Oridion MicroCap Plus/NPB-75 is substantially equivalent to the pulse oximeter module MP204 (Nellcor Puritan Bennett) in the cleared device being modified.

Substantial Equivalence Information

The modified device, the MicroCap Plus/NPB-75, is a two parameter monitor incorporating the functions of the currently marketed two parameter monitor. It is substantially equivalent, in terms of indications for use and technological characteristics to the two parameter Oridion MicroCap Plus/NPB-75 (K964239) capnograph/ pulse oximeter.

CLASSIFICATION Class II 73CCK

The MicroCap Plus /NPB-75 capnometer/pulse oximeter is a device that combines two devices that have been classified as follows:

21 CFR, Section 868.1400, carbon dioxide analyzer. The capnometer device measures the concentration of carbon dioxide in a gas mixture by the use of infrared radiation as described in 868.1400. Its classification is Class II (performance standards). Since no performance standards have been issued, it will be regulated by the Special Controls provision of the Act.

21 CFR, Section 870.2700, oximeter. This is a device that is used to transmit radiation at known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. Its classification is Class II (performance standards). Since no performance standards have been issued, it will be regulated by the Special Controls provision of the Act.

Differences Between The Microcap Plus /NPB-75 and the modified device.

The cleared Microcap Plus/NPB-75 device uses the NPB MP204 SpO_2 module and the modified Microcap Plus/NPB-75 device uses the NPB MP507 SpO_2 module The MP507 module takes advantage of the current availability of smaller mechanical, electrical and electronic components with lower operating power requirements. The basic design, intended use and indication of the NPB-75 remain the same and the design modifications have not altered the fundamental scientific technology, materials or manufacturing processes of the NPB-75. The changes pose no new issues of safety or efficacy.

Flow And Gas Sampling System

The MicroCap Plus /NPB-75 and the modified device use the identical flow and gas sampling system and pneumatic system

Oximeter module

The Oximeter module used in the modified MicroCap Plus /NPB-75 device is the MP507 module supplied by Nellcor Puritan Bennett. It is considered an improved version of the MP204 module. It is essentially equivalent to the MP204 module supplied by Nellcor Puritan Bennett and used by Oridion in the MicroCap Plus/NPB-75 (K964239).

Intended Use

The MicroCap Plus/NPB-75 combined capnograph/pulse oximeter monitor (cleared and modified device) is intended for:

1) Use by physicians, nurses and other trained health care providers in critical care patient settings, such as Anesthesiology, intensive care medicine, Neonatal Intensive Care, Transport, EMS and other health care areas where non invasive measurement of expired CO_2, inspired CO_2, breath rate, SpO_2 and pulse rate are of medical value.

2) The continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate.

3) The continuous, non invasive measurement and monitoring of arterial oxygen saturation (SpO_2) and pulse rate.

4) The monitors can be powered through an external line powered DC power supply or can be battery operated.

The intended use and indication of the NPB-75 remain the same and the design modifications have not altered the fundamental scientific technology, materials or manufacturing processes of the NPB-75. The changes pose no new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2003

Mr. Sandy Brown
Regulatory Affairs Director
Oridion Medical 1987 Limited
Har Hotzvim Industrial Park
P.O. Box 45025 / HaMarpe 7
Jerusalem,
ISRAEL 91450

Re: K024300
Trade/Device Name: MicroCap Plus/NPB-75
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA , CCK
Dated: March 13, 2003
Received: March 17, 2003

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. Indications for Use Form

December 22, 2002

Device Name:

MicroCap Plus/ NPB-75

Indications For Use:

The MicroCap Plus /NPB-75 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 of arterial oxygen saturation (SpO_2) and pulse rate.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K024300