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Section 5 - 510(k) Summary of Safety and Effectiveness

K071610

Submitter Information:
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NOV - 5 2007

Date Prepared:
May 2nd 2007

Product Name & Classification:
Mediaid Model# M30 and M34
Common Name: Pulse Oximeter
Regulation: 870.2700
Product Code: DQA
Class: II

Predicate Device:
Mediaid (formally Palco Labs) Pulse Oximeter Model 34 is substantially equivalent to Mediaid / Palco Pulse Oximeter Model 305 marketed under K943842 and Nonin Model 2500 marketed under K050056. Comparative matrices between the proposed devices and other devices are provided. Please refer to section 12.

Model 34 is identical to other marketed devices, with the exception that the power source battery is Li-ion and USB port is added to the existing topography of Mediaid/Palco Pulse Oximeters.

Description:
The Mediaid Pulse Oximeter Model 34 is designed to measure the percentage of functional oxygenated hemoglobin to total hemoglobin.

Noninvasive arterial oxygen saturation measurement is obtained by directing red and infra red light through a pulsating vascular bed. The pulsating arterioles in the path of the light beam cause a change in the amount of light detected by a photodiode. The pulse oximeter determines the oxygen saturation of arterial blood by measuring the ratio of transmitted red to infrared light within the pulse waveform. The non-pulsatile signal is removed electronically for the purpose of calculation. Therefore, skin, bone, and other non-pulsating substances do not interfere with the measurement of arterial oxygen saturation.

Product images are included. Please refer to section 11.

Intended Use:
Mediaid pulse oximeter model 34 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in hospitals, physician's offices, emergency medical facilities, or at home. The model 34 can store data in memory for later review and documentation and also features a sleep mode for Basic overnight screening.

Comparison to Predicate Device:
Mediaid SpO2 Sensors use the same theory and principle of operation as the predicate device. Design characteristics are equivalent in terms of safety and effectiveness, as demonstrated by product testing and accuracy claims.

Performance Data & Conclusions:
Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. Mediaid Pulse Oximeter Model 34 were compared to arterial blood samples analyzed on a laboratory co-oximeter and found to be equivalent to predicate device accuracy claims. Bench testing was performed to verify pulse rate accuracy.

Biocompatibility, electrical safety, and EMC testing were also performed to demonstrate conformance with established industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Mr. Jayesh Patel
Chief Executive Officer
Mediaid, Incorporated
17517 Fabrica Way, Suite H
Cerritos, California 90703

Re: K071610
Trade/Device Name: Mediaid Pulse Oximeter M30 and M34
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 22, 2007
Received: October 24, 2007

Dear Mr. Patel:

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

Indications for Use

510(k) Number: K071610

Device Name: Mediaid Pulse Oximeter M30 and M34

Indications for Use: Non-invasive measurement of arterial oxygen saturation and pulse rate in hospitals, physician's office, emergency medical facilities, or at home. The model 34 can store data in memory for later review and documentation and also features a sleep mode for basic patient sleep screening.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K071610