MAY - 2 2008

K071642

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

1. Submitter Information:

Mediaid, Inc.
17517 Fabrica Way #H
Cerritos, CA 90703
Registration # 2087439

2. Contact:

Jayesh Patel, CEO
Telephone: 714-367-2848
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3. Date Prepared:

April 1st, 2008

4. Description:

Trade Name: Mediaid M960 Series, Vital Signs Monitor and Mediaid M900 Series, Pulse Oximeter
Common Name: Vital signs measurement devices
Name: Non-invasive pulse Oximeter, SpO2 (21CFR870.2700), also contains NIBP measurement system (21CFR870.1130) and clinical electronic thermometer (21CFR880.2910)
Classification: Class II

Trade Name: Mediaid M900 Series, Pulse Oximeter
Common Name: Pulse Oximeter
Name: Non-invasive pulse Oximeter, SpO2 (21CFR870.2700)
Classification: Class II

The Mediaid Vital Signs monitor Pulse Oximeter Model M960P provides real time monitoring and display of oxygen saturation of arteriolar hemoglobin (SpO2), Non Invasive Blood Pressure, pulse rate and body temperature. Where as the Mediaid Pulse Oximeter Model M900 provides real time monitoring and display of oxygen saturation of arteriolar hemoglobin (SpO2) and pulse rate only.

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.

Non invasive blood pressure is intended to non invasively measure systolic, diastolic and mean arterial pressures (MAP).

Temperature- Thermometer takes patient temperature in oral, axillary or rectal mode.

5. Substantial Equivalence:

The Mediaid Pulse Oximeter Model 900 is substantially equivalent to the following devices:

- Model 305 of Mediaid Palco marketed under K943842
- Model 340 of Mediaid Palco marketed under K920066
- Model 120 of Mediaid Palco marketed under K994372

The Mediaid Vital Signs Monitor Model 960 series is substantially equivalent to the following devices:

For Pulse Oximeter :

- Model 305 of Mediaid Palco marketed under K943842
- Model 340 of Mediaid Palco marketed under K920066
- Model 120 of Mediaid Palco marketed under K994372

For Ni-BP Monitor:

- Welch Allyn Spot Ultra Vital Signs marked under K040490
- Tango+Automatic Blood pressure and Oxygen Saturation Measurement System of Suntech Medical Inc Marketed under K053209.

For Clinical Thermometer:

- Welch Allyn Spot Ultra Vital Signs marked under K040490

Intended Use:

Indications for Use

The Model 960 Series is a desktop monitor intended for use as a continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, non invasive blood pressure and temperature. The intended patient population comprises adult, and pediatric weighing more than 5Kg. The intended environment of use is hospital environment. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas within the hospital plus hospital-type facilities such as surgical centers, sub-acute centers, special nursing facilities and sleep labs. The Model 900 is an Pulse Oximeter only.

WARNING: The Model 900 and 960 Series is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

510(k) Number (if known): K071642

Device Name: Mediaid M960, and M960P Vital Signs Monitor and Mediaid M900, Mediad 900P Pulse Oximeter

Comparison to Predicate Device:

Mediaid Pulse Oximeter Model 900 series and pulse Oximeter module of Model 960 series uses 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.

Mediaid uses Suntech Medical Inc's Advantage OEM BP Module in Model 960 series. This module is compared with Tango+Automatic Blood Pressure and oxygen saturation measurement system of Suntech Medical Inc. NiBP module of Welch Allyn Spot Ultra Vital Signs monitor. It is observed that design characteristics are equivalent in terms of safety and effectiveness, as demonstrated by product testing and accuracy claims.

Mediaid use YSI compatible temperature probe for temperature measurement and its performance is compared with the thermometer module of Welch Allyn Spot Ultra Vital Signs monitor. It is observed that design characteristics are equivalent in terms of safety and effectiveness, as demonstrated by product testing and accuracy claims.

Technological Characteristics

A comparison of the technological characteristics of Model 960 Vital Signs Monitor and the predicate devices has been performed. The results of this comparison demonstrate that the Model 960 series is substantially equivalent to the marketed predicate devices in technological characteristics.

Environmental and non-clinical testing

Applicable environmental and non-clinical testing was performed per IEC60601-1 and IEC 60601-1-2 as well as other applicable standards and procedures. The Mediaid Pulse Oximeter Model 960 series passed all tests as per the requirements of various applicable international standards.

Performance Data & Conclusions:

Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. Mediaid Pulse Oximeter Model 900 series readings 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.

For Ni-BP, clinical study was conducted by Suntech Medical Inc on their OEM module and the results show that the claimed accuracy is met as per the requirement of IEC 60601-2-30 and AAMI SP10.

Clinical Tests for Clinical thermometer is conducted on an external hospital and the results shows that the thermometer module of Model 960 series meets the claimed accuracy as per ASTM E 1112:00 and EN 12470-4

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

MAY - 2 2008

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

Re: K071642
Trade/Device Name: Mediaid M960, and M960P Vital Signs Monitor and Mediaid M900, Mediaid 900P Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DXN
Dated: April 24, 2008
Received: April 28, 2008

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) 276-0115. 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

Section 4 - Indications for Use Statement

Detailed instructions are given in the user's manual.

Indications for Use

The Model 960 Series is a desktop monitor intended for use as a continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, non invasive blood pressure and temperature. The intended patient population comprises adult, and pediatric weighing more than 5Kg. The intended environment of use is hospital environment. Hospital use typically covers areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas within the hospital plus hospital-type facilities such as surgical centers, sub-acute centers, special nursing facilities and sleep labs. The Model 900 is an Pulse Oximeter only.

WARNING: The Model 900 and 960 Series is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

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Device Name: Mediaid M960, and M960P Vital Signs Monitor and Mediaid M900, Mediad 900P Pulse Oximeter

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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