K100225

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510(k) Summary of Safety and Effectiveness

Submitter

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Date Summary Prepared: July 20th, 2010

Device Name

Trade Name:	P10, Pulse Oximeter
Common Name:	Pulse Oximeter
Classification Name:	Non-invasive pulse oximetry, SpO_2 (21CFR870.2700)
Classification:	Class II
Product code:	DQA

Predicate Devices (Legally Marketed Devices)

The predicate devices for Pulse oximeter, P10 is:

- **Nellcor Puritan Bennett** (division of Tyco Healthcare Inc.) Handheld Pulse Oximeter, Model NPB-40 cleared by FDA through 510(k) No. **K963707**, and
- **Mediaid inc.** Pulse Oximeter, Model 3X Series cleared by FDA through 510(k) No. **K071610**, and
- **Masimo Corp.** Masimo SET Pulse Oximeter, Model RAD-5 cleared by FDA through 510(k) No. **K033296**.

Device Description

The P10 Pulse Oximter is to monitor non-invasive functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric and neonate patients in general hospital and alternate care facilities by medically trained personnel. This monitor is available for sale only upon the order of a physician or licensed health care professional.
The Mediana P10 Pulse Oximeter is a lightweight and compact device (58×105×21mm and 90g) powered by 3 Alkaline AAA batteries. The monitor provides patient data and monitoring status on LCD displays. MD1 module is used for SpO_2 module, and YM-1 reusable sensor is used for SpO_2 sensor.

Intended Use

The P10 pulse oximeter is intended to be used to monitor functional arterial oxygen saturation (SpO_2) and pulse rate in all areas of a hospital, hospital-type facilities, intra-hospital transport and home environments. Users should be skilled at the level of a technician, doctor, nurse or medical specialist.

Note: The continuous monitoring and Spot check mode are user-selectable. The mode of operation is the continuous monitoring except when the Spot Check Mode (03) is enabled.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Mediana pulse oximeter, Model P10 is substantially equivalent to the Mediaid inc., Model 3X series, Masimo, Model RAD-5, and Nellcor Puritan Bennett (division of Tyco Healthcare Inc.), Model NPB-40.

- The **Pulse Oximetry (SpO_2)** specifications and performance are equivalent to the Mediaid inc., model 3X Series and Masimo Corp., model RAD-5. The P10 pulse oximeter uses the SpO_2 module (MD1) and the SpO2 sensor (YM-1, YM-2 and YM-5). The SpO_2 module (MD1) has the clinical validation report. A copy of the clinical report mentioned is in Section 17-O at the end of the 510(K) submission files. The operation principle of Mediana Model P10 is same as those of the Mediaid inc., model 3X series, the Masimo, model RAD-5 and Nellcor Puritan Bennett, model NPB-40. (The units measure functional saturation – oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen.)
- The **Pulse rate (PR)** specifications and performance derived from Non-Invasive Pulse Oximetry (SpO_2) are equivalent to the Mediaid inc., model 3X Series and Masimo Corp., model RAD-5.

Summary of Performance Testing in order to demonstrate substantial equivalence

The Mediana pulse oximeter, Model P10 substantially have been tested in accordance with the system V & V plan and summary (#MDR-YW090626-01) included with the submission using production equivalent units prior to release to market.

Biocompatibility(ISO 10993), electrical safety(ISO 60601-1), EMC(ISO 60601-1-2) and SpO_2 (ISO 9919) testing were also performed to demonstrate conformance with established industry standards. These standards are applicable for predicate devices in common.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Mediana design control procedure. Mediana's quality system confirms to 21CFR820, ISO 9001, ISO13485 and CMDCAS ISO 13485 certified by DNV (Det Norske Veritas) and QMI (Quality Measuring Instrument).

Clinical Tests Submitted

Clinical hypoxia testing was performed under an institutionally approved protocol with subject informed consent. Clinical testing was performed with human adult volunteers to validate the accuracy of P10 pulse oximeter with accessory sensors versus arterial oxygen saturation(SaO_2) as obtained by co-oximetry reference method on radial arterial blood samples. No adverse events or complications were noted during the study.

The list of human adult volunteers is shown below.

Subject #	Age	Race	Sex	Physical Condition
1	27	White	M	6'0", 225lb
2	21	White	M	6'0", 180lb
3	26	White	M	5'11", 205lb
4	21	Hispanic	F	4'11", 105lb
5	29	White	F	5'6", 148lb
6	20	White	F	5'4", 140lb
7	28	African American	M	6'0", 190lb
8	23	White	M	5'7", 150lb
9	34	Hispanic	F	5'1", 113lb
10	30	Hispanic	M	5'7", 175lb

Sample(SpO_2) and reference(SaO_2) values were evaluated for A_{RMS} accuracy in accordance with recognized methods. Data obtained from the clinical tests support device accuracy claims for the specified saturation range.

As described above, testing above demonstrates that the P10 pulse oximeter monitor with accessory sensors are equivalent to predicate sensors as substantiated by laboratory and clinical testing.

Device safety is supported by use of biocompatible patient contact materials and compliance testing to recognized standards.

Conclusions

As stated above, the Mediana pulse oximeter, Model P10 is safe and effective and complies with the appropriate medical device standards and is substantially equivalent to the earlier identified predicate devices.

- End of Section -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Mediana Company, Limited
C/O Mr. Charlie Mack
International Regulatory Consultants
77325 Joyce Way
Echo, Oregon 97826

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Re: K100225
Trade/Device Name: P10, Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Pulse Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 3, 2011
Received: February 7, 2011

Dear Mr. Mack:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

Applicant:
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510(k) Number: _____

Device Name: P10, Pulse Oximeter

Indications for Use:

The P10 pulse oximeter is intended to be used to monitor functional arterial oxygen saturation (SpO_2) and pulse rate in all areas of a hospital, hospital-type facilities, intra-hospital transport and home environments. Users should be skilled at the level of a technician, doctor, nurse or medical specialist.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____O____ OR Over-The-Counter_____
(Per 21CFR801.109)

- End of Section (Sign-Off)

vision of Anesthesiology, General Hospital
fection Control, Dental Devices

10(k) Number: K100225