



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Oxypulse
C/O Mr. James A. Dunning
President
Qualpro Consulting, LLC
One Macdonald Center, 1 North Macdonald Suite # 8
Mesa, Arizona 85201

JUN 16 2010

Re: K100815

Trade/Device Name: OxiBlue Fingertip Pulse Oximeter and OxiPro Fingertip Pulse Oximeter

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: II

Product Code: DQA

Dated: March 18, 2010

Received: March 23, 2010

Dear Mr. Dunning:

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,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", followed by the word "for" in a smaller, less distinct script.

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

Indication for use

510(k) Number (if known): K100815

Device Name: OxiBlue Fingertip Pulse Oximeter and OxiPro Fingertip Pulse Oximeter

Indications for Use:

The OxiBlue Fingertip Pulse Oximeter is indicated for continuous or spot-checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals and home care. It is intended for adult and pediatric patients on finger between 0.3-1.0 inch (0.8 - 2.5 cm) thick. The OxiBlue can transmit data via either a USB cable or wireless Bluetooth technology.

The OxiPro Fingertip Pulse Oximeter is indicated for continuous or spot-checking in measuring and displaying functional arterial oxygen saturation (SpO2) and pulse rate of patients in hospitals and home care. It is intended for adult and pediatric patients on finger between 0.3-1.0 inch (0.8 - 2.5 cm) thick. The OxiPro can transmit data via a USB cable, and does not include Bluetooth technology.

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



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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