510(K) SUMMARY (SPECIAL)

MAR - 8 2010

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Date the Summary was Prepared

December 31, 2009
February 25, 2010 (Revised)

Device/Trade Name/Common Name/Classification

Device Names (Proprietary/Trade Names):	DX Finger Sensor, DX Y-Sensor, (DX Series Sensors)
Device Name (Common Name):	Pulse Oximeter Sensors
Classification:	Class II, 21CFR 870.2700/74DQA

Legally Marketed Predicate Devices

Legally marketed predicate devices to the DX Series Sensors:

- Novametrix 8776-00 Finger and 8791-00 Wrap (Y) Sensor (K993979)
- Novametrix' Marquette Compatible 9752-00 Finger and 9753-00 Wrap (Y) Sensor (K010451)
- Nellcor DS100A Adult Finger Clip Sensor and D-YS Multisite Sensor
- Philips M1196A Adult SpO_2 Clip Sensor, M1191A Soft Glove Sensor (series) and M1194A Ear Clip Sensor.

Description of the Subject Device

The DX Series Pulse Oximeter Sensors combine the operational characteristics of pulse oximetry sensors that have already received Substantially Equivalent determination from FDA (K993979 and K010451) into new Finger Sensor and Y-Sensor configurations that, like the predicate devices, share the same outward

physical designs and fundamental scientific technology. The modification enables a sensor to be used with Dixtal's existing pulse oximeter monitor devices as currently listed, as well as to function with other pulse oximetry products. The modified sensors allow healthcare practitioners to more widely standardize pulse oximetry sensors and applicator accessories, and to minimize potential Human Factors issues that might result from using sensors and applicator accessories from multiple manufacturers.

Statement of Intended Use

The new DX Series Pulse Oximeter Sensors are reusable (multi-patient-use) sensors intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, infant, pediatric and adult patients, in environments where pulse oximetry monitors or modules in multi-parameter systems are indicated for use, when in the judgment of a licensed medical practitioner/physician pulse oximetry is required.

Technological Characteristics

The new DX Series Sensors share the same outward physical designs, including materials and assembly processes, and the same fundamental scientific technology as the predicate devices (K993979 and K010451). The modification brings the designs of both listed predicates into a single sensor without using new or modified electro-optical components. The modified design operates as either one predicate device or the other—but not both—as dictated by the requirements of the pulse oximeter or oximeter/adapter cable combination to which it is attached. Bench testing and in vivo testing have confirmed equivalent performance.

A further discussion of the scientific technology can be found at Section 8 of the submission, while a more general discussion of the operational characteristics of pulse oximetry sensors is attached as Appendix 1.

Performance Data

Non-clinical data

Biocompatibility Testing: this evaluation was previously performed (2003 and 2006). We determined that repeat of the Biocompatibility Testing was unnecessary since we are using the identical materials as used in our current Finger and Y Sensors. The report documents testing compliant to ISO 10993-1:2003.

SpO_2 Sensor LED Temperature Test: Sensor testing was performed in an environmental chamber consistent with the requirements of ISO 9919:2005. The maximum temperature recorded was below 41 degrees C.

DX Sensor Bench Testing: Engineering bench studies were performed and documented using the intended mating device. We performed testing with Philips and Nellcor monitors comparing their performance to Dixtal monitors, all using the DX Series Sensors. Performance was determined to be equivalent.

DX Sensor Cleaning: Engineering performed a sensor cleaning evaluation to verify the cleaning agents recommended for use to clean and achieve low level disinfection of the Finger and Y Sensors are compatible with the sensor materials.

EMC Evaluation: The DX Series sensors with the extension cables were evaluated at the Philips Andover facility. Testing included Emissions and Immunity as well as ESD evaluation with results compliant to the requirements of the EMC related standards.

Hazards Analysis: Results of a Hazards Analysis for the DX Series SpO_2 Finger and Y Sensor were documented and are included in this submission. We concluded that the devices are safe and effective for their intended use.

Clinical data

Controlled de-Sat Testing of DX Series Sensors: Testing was performed under IRB authorization from University of Southern California at San Francisco (Bickler, formerly Severinghaus) in compliance with ISO 9919:2005. The study included 24 healthy, non-smoker, subjects (with informed consent), half male and half female, ages 22-32. None were anemic and skin tone varied from light to dark. No adverse events or complications were noted. Based upon statistical standards (as noted in the report) clinical performance and accuracy of the DX Series Sensors is equivalent to the tested predicate devices.

Clinical Evaluation: Clinical Evaluation was initiated in a Brazilian Healthcare Facility (Irmandade da Santa Casa de Misericórdia de Porto Alegre) after receipt of written authorization from the Facility's (registered) IRB. The testing is focused upon Neonatal patients (and some Pediatric patients) to ensure we comply with the intent of Section 7.2 In Vivo testing for SpO_2 accuracy for neonates, in the FDA Draft Guidance for Pulse Oximeters – Premarket Notification Submissions [510(k)s], dated July 19, 2007. No adverse events or complications have been noted.

Literature Review: A literature review was conducted and documented as part of our product evaluation. The report includes a discussion of motion and simulator testing however there were no significant issues identified that required further evaluation.

Conclusion:

In compliance with Guidance Documents, accepted Industry Standards, and Design Control requirements, the documented results of verification and validation testing, inter-device (Dixtal, Nellcor, Philips) comparison studies, and hypoxia studies, establish; the equivalent accuracy of DX Series Sensors to sensors manufactured for use with other pulse oximeter equipment, and that the Dixtal DX Series Sensors are Substantially Equivalent to the predicate devices.

Appendix 1 — Pulse Oximetry-Background

Pulse Oximeters to which these sensors are connected measures oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation.

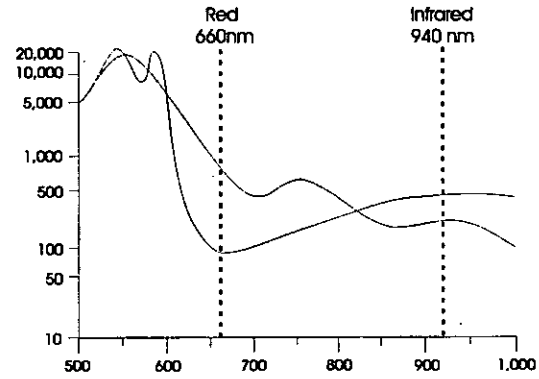
The light energy from red (660 nm) and infrared (880nm or 940 nm) LEDs is beamed through a sample cell- a pulsating vascular bed, the patient's finger or toe for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered and displayed as a numerical value for oxygen saturation and as a waveform, the Plethysmogram.

Functional oxygen saturation is defined as: percentage saturation given by the oxyhemoglobin concentration (cO2Hb) divided by the sum of the oxyhemoglobin concentration and the deoxyhemoglobin concentration (cHHb)

Fractional oxyhemoglobin FO2Hb: oxyhemoglobin concentration cO2Hb divided by the total hemoglobin concentration, ctHb where; cO2Hb is the concentration of oxyhemoglobin; ctHB is the concentration of total hemoglobin.

This is sometimes reported as a percentage (multiplying the fraction by 100).

Functional saturation represents the amount of oxyhemoglobin as a percentage of the hemoglobin that can be oxygenated. Dysfunctional hemoglobin (COHb and METHb) are not included in the measurement of functional saturation.



Pulse Oximetry - Extinction Coefficients vs. wavelength (nm)

Pulse rate is calculated by measuring the time interval between the peaks of the infrared light waveform.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAR - 8 2010

Re: K100020
Trade/Device Name: Dixtal DX Series SpO_2 Sensors
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: February 11, 2010
Received: February 12, 2010

Dear Mr. Schiffman:

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

510(k) Number (if known)

Device Name: Dixtal DX Series SpO_2 Sensors

Indications for use: DX Series Pulse Oximeter Sensors are multi-patient-use sensors intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, infant, pediatric and adult patients, in environments where pulse oximetry monitors or modules in multi-parameter systems are indicated for use, when in the judgment of a licensed medical practitioner/physician pulse oximetry is required.

Prescription Use _____ **AND/OR** **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **(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

510(k) Number: K100020