K102350

DEC 2 2 2010

510(k) Summary

Submitter: Nonin Medical, Inc.

Contact Person:
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Date Prepared: August 18, 2010

Trade Name: Model 3150 WristOx$_2$

Classification Name: and Number: Class II, 21 CFR 870.2700

Product Code: DQA

Predicate Device(s): This submission demonstrates that the modified Model 3150 WristOx$_2$ is substantially equivalent to Nonin's Model 3100 WristOx® based on clinical, performance and safety testing. Validation test results do not raise new questions of safety and effectiveness when compared to the legally marketed devices.

Device Description: Model 3150 is a wrist-worn device with memory for patient data collection and Bluetooth wireless communication capability. The device is a simple-to-use pulse oximeter for both long and short term measurements. The device can be integrated into a telemedicine system, interfaced to other health data collection systems through the wireless connection, or used with Nonin's nVISION® Data Management Software K033307.

The basic functions of the Model 3150 with an external sensor will be:

- Measurement of SpO2 and pulse rate,
- Motion artifact detection,
- Collection and storage of data, and Communication via a wired connection and / or Bluetooth wireless connection.

Technical Summary of the Bluetooth Module

- Bluetooth 2.0 is an embedded module communicating over the Serial Port.
- It utilizes a STLC2500C HCI Bluetooth transceiver and a LPC2138FHN64/01 ARM7 microcontroller running the t.Blue Bluetooth Stack.
- The module has on-board connectors that allow it to communicate to an oximeter device microcontroller either via hardware or software asynchronous serial communication interface.

The module is designed to automatically switch the output transmit power between Bluetooth Class 1 (16 dBm) and Bluetooth Class 2 (4 dBm), conserving battery life and reducing unnecessary RF emissions.

Intended Use:

Nonin's Model 3150 WristOx$_2$ Pulse Oximeter is a small wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients. It is intended for spot-checking and / or data collection and recording of patients who are well or poorly perfused. The intended use environments are sleep and pulmonary rehab labs, surgical recovery, critical care, emergency room, long-term care, home use and mobile units.

Functional and Safety Testing:

Nonin's Model 3150 WristOx$_2$ pulse oximeter has successfully undergone both bench and clinical testing in order to demonstrate that it meets the requirements of ISO 9919:2005 Clause 50 Accuracy of Operating Data, Clause 102 section 102.2 Labeling, and IEC 60601-1:1998 (ISO 10993-1:2003) Clause 48 Biocompatibility.

Conclusion:

This submission demonstrates that the modified Model 3150 WristOx$_2$ is substantially equivalent to Nonin's Model 3100 WristOx® based on clinical, performance and safety testing. Validation test results do not raise new questions of safety and effectiveness when compared to the legally marketed devices.

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

Ms. Lori M. Mitchell
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Plymouth, Minnesota 55441-5443

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Re: K102350
Trade/Device Name: Model 3150 WristOx$_2$ Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 14, 2010
Received: December 15, 2010

Dear Ms. Mitchell:

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

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Indications for Use Statement

510(k) Number (if known) K102350

Device Name Model 3150 WristOx$_2$ Pulse oximeter

Indications for Use

The Nonin Model 3100 WristOx™ Pulse Oximeter is a small, wrist-worn device indicated for use is measuring, displaying and storing functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate. It may be used for spot-checking and/or data collection and recording of adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The intended use environments are hospitals, medical facilities, ambulatory, subacute, sleep study environments, and mobile units.

Prescription Use ____X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 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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