NOV 10 2005

510(k) Summary K052829

Submitter: Nonin Medical, Inc.

Contact Person:
Lori Roth
Clinical/Regulatory Specialist
Nonin Medical, Inc.
13700 1st Ave. North
Plymouth, MN 55441-5443

Date Prepared: October 3, 2005

Trade Name: Model 3100 WristOx® Pulse Oximeter

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

Product Code: 74 DQA

Predicate Device(s): Model 3100 WristOx® is substantially equivalent to the Model 3100 WristOx® (K030668), which is also manufactured by Nonin Medical.

Device Description: The Nonin Model 3100 WristOx® is a small wrist-worn pulse oximeter. It has an electro-optical sensor that determines the light absorption of functional arterial hemoglobin. It is used to spot check patients, or it can be used to provide continuous data collection and recording of patients in situations where alarms are not required. The device turns on automatically when the sensor is placed on the finger and turns off when the finger is removed. It may be used with Nonin's 8000AA-WO articulated finger clip sensor or the 8000J-WO flex sensor. The WristOx is also memory capable in conjunction with nVision® data management software (K033307). It is capable of storing up to 33 hours of SpO_2 and pulse rate data.

Intended Use: The Nonin® Model 3100 WristOx® 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 during both no motion and motion conditions, and for patients who are well or poorly perfused.

Functional and Safety Testing:

Nonin's Model 3100 WristOx® Pulse Oximeter has successfully undergone both bench and clinical testing in order to demonstrate that it has appropriate functional characteristics and is substantially equivalent to the predicate device.

Conclusion:

Nonin's Model 3100 WristOx® Pulse Oximeter is identical in everyway to the predicate device not with standing the changes specified in the labeling.

This conclusion is based upon the fact that the Model 3100 WristOx® Pulse Oximeter is substantially equivalent to the predicate device in terms of functional design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Lori Roth
Clinical/Regulatory Specialist
Nonin Medical, Incorporated
13700 1st Avenue North
Plymouth, Minnesota 55441-5443

Re: K052829
Trade/Device Name: Model 3100 WristOx® Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 1, 2005
Received: October 13, 2005

Dear Ms. Roth:

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.

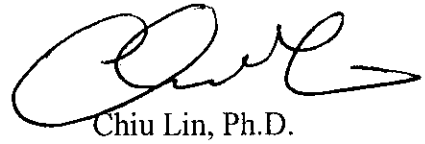
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known) _____

Device Name Nonin Medical, Inc. Model 3100 WristOx® Pulse Oximeter

Indications for Use

The Nonin® Model 3100 WristOx® 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 during both no motion and motion conditions, and for patients who are well or poorly perfused.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(21 CFR 807 Subpart C)

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

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