OCT 17 2003

Summary and Certification

A 510 Summary, K030668

Submitter:	**Nonin Medical Inc.**
Contact Person:	**John R. Dalpee** **Director, Regulatory Affairs** **Nonin Medical Inc.** **2605 Fernbrook Lane N.** **Plymouth, MN 55447-4755**
Date Prepared:	**150October, 2003**
Trade Name:	**WristOx™ Pulse Oximeter, Model 3100**
Classification Name And Number:	**Class II, 21 CFR Part 870.2700, Oximeter**
Product Code:	**DQA**
Predicate Device:	**Model 2500 PalmSat® Hand Held Pulse Oximeter (K002690)**

Device Description: The Nonin Model 3100 WristOx is a small, wrist worn pulse oximeter. It uses an electro-optical sensor to noninvasively measure, display and store functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. The WristOx stores up to 33 hours of SpO2 and pulse rate data. Stored patient data may be downloaded to any data management software system using the non-proprietary communication protocol . Nonin's data management software system (nVISION™) is available as an accessory, but is not required to use the memory feature

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 (SpO2) and pulse rate. It may be used for spot-checking and/or data collection and recording of adult and pediatric patients in hospitals, medical facilities, ambulatory, subacute and sleep study environments.

Functional and Safety Testing: The Nonin Model 3100 WristOx has 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: The Nonin Model 3100 WristOx is substantially equivalent to the Model 2500 PalmSat Hand Held Pulse Oximeter (K002690), which employs a similar memory function. This conclusion is based on the fact that the subject device is substantially equivalent to the predicate device in terms of principals of operation, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. John R. Dalpee
Director of Regulatory Affairs
Nonin Medical Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Re: K030668
Trade/Device Name: WristOx Pulse Oximeter, Model 3100
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 29, 2003
Received: July 30, 2003

Dear Mr. Dalpee:

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 (301) 594-4646. 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/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
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 K030668
Device Name; WristOx Model 3100

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 (SpO2) and pulse rate. It may be used for spot-checking and/or data collection and recording of adult and pediatric patients in hospitals, medical facilities, ambulatory, subacute, and sleep study environments.

Concurrence of CDRH, Office of Device Evaluation

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

510(k) Number: K030668