K043359

JAN - 7 2005

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Nonin Medical, Inc.

Contact Person:
John R. Dalpee
Director of Regulatory Affairs
Nonin Medical, Inc.
2605 Fernbrook Lane N.
Plymouth, MN 55447-4755

Date Prepared: December 6, 2004

Trade Name: Model 4100 Patient Oximeter Module

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

Product Code: 74 DQA

Predicate Device(s): Nonin's Model 4100 Patient Oximeter Module is substantially equivalent to the Avant® Model 4000 Pulse Oximetry System manufactured by Nonin Medical, Inc. that was cleared by the FDA under K041156 on 6/09/04.

Device Description: Nonin's Model 4100 Bluetooth® - enabled wrist-worn Patient Oximeter Module measures and transmits SpO_2, pulse rate, and plethysmographic data to a compatible Bluetooth – enabled device. The patient module includes a class II Bluetooth radio with a range of approximately 30 feet (spherical range).

The 4100 Patient Oximeter Module is powered with two AA batteries, which last for approximately 120 hours when used continuously.

Intended Use: The Nonin® Bluetooth® - enabled Model 4100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible Bluetooth – enabled device.

Functional and Safety Testing:	Nonin's Model 4100 Patient Oximeter Module has successfully undergone both bench and clinical testing in order to demonstrate that it has appropriate functional features and is substantially equivalent to the predicate device.
Conclusion:	Nonin's Model 4100 Patient Oximeter Module is substantially equivalent to the Avant® Model 4000 Pulse Oximetry System manufactured by Nonin Medical, Inc. and cleared by the FDA under K041156 on 6/09/04.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2005

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

Re: K043359
Trade/Device Name: Model 4100 Patient Oximeter Module
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 6, 2004
Received: December 17, 2004

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) 594-0120. 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/dsma/dsmamain.html

Sincerely yours,

Suzette Michaud MS.

Chiu Lin, Ph.D. for DR. LIN
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 Statement

510(K) Number: K043359

Device Name:

Nonin Medical, Inc. Model 4100 Patient Oximeter Module

Indications for Use:

The Nonin Bluetooth® - enabled Model 4100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to a compatible Bluetooth® enabled device.

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

510(k) Number: K043359

Richard for DR. CHIU LIN 01-07-05

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)