DEC 2 3 2005

K 052669

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Nonin Medical, Inc.

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

Date Prepared: October 17, 2005

Trade Name: Avant® Model 4000 Digital Pulse Oximetry System

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

Product Code: 74 DQA

Predicate Device(s): Nonin's Avant® Model 4000 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 06/09/04.

Device Description: The Avant Model 4000 Digital Pulse Oximetry System is a wireless pulse oximeter that includes a portable, tabletop display unit (Avant 4000) and a wrist-worn patient module Avant (4100). The system determines arterial oxyhemoglobin saturation (SpO_2) by measuring the absorption of red and infrared light passed through the tissue. Changes in absorption caused by pulsation of blood in the vascular bed are used to determine arterial saturation and pulse rate. Using Bluetooth® wireless technology, the system allows functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and plethysmographic data to be transmitted from the wrist worn (4100) module to a compatible Bluetooth-enabled device tabletop monitor (4000).

Bluetooth wireless technology is used in the Avant, Model 4000 Pulse Oximetry System to transmit data from the 4100 Patient Module to the 4000 Display Unit. The technology allows replacement of simple point-to-point

cabling. The low power radio (used in the Avant System) covers 30 feet (spherical radius) with a total bandwidth of 1 Mbps, and a theoretical 720 kbps data payload. The Bluetooth radio is highly immune to noise and simple to implement on silicon and software. In order to achieve robust connections, Bluetooth employs several techniques: very fast frequency hopping, several layers of checks and Cyclical Redundancy Checks (CRCs), packet retransmission, and relatively short data packets. Bluetooth offers the features of robust security and authentication, using the SAFER+ algorithm with 128 bit keys for secure encryption and authentication. The Avant Model 4000 has been tested and verified to meet the specifications of the Bluetooth revision 1.1 and is listed by the Bluetooth SIG (Special Interest Group). It implements the Generic Access Profile (GAP) and Serial Port Profiles and fully implements security and authentication. The Avant Model 4000 System has also been granted Federal Communications Commission (FCC) authorization.

Nonin's system eliminates the connection from the wrist-worn oximeter module (4100) to the display unit (4000), giving patients increased ability to move freely without being hindered by cables. Nonin's patient module uses a class II Bluetooth radio with a battery life of approximately 120 hours and a range of approximately 30 feet (spherical radius). The display unit has a minimum operating life of 18 hours with a fully charged battery. When the AC adaptor is plugged into the display unit, power is divided between operating the device and charging the battery pack. The display unit can also be used continuously with the AC adaptor.

The Avant 4000 display uses light-emitting diodes (LED) components to present patient's SpO_2 and pulse rate values, as well as alarm limit and volume settings. The Avant™ 4000 can be powered with a 12 VDC AC adapter or with an integral sealed 7.2-volt rechargeable NiMH battery pack. The Avant 4100 patient module is powered with two 1.5-volt AA batteries.

The Avant 4000 System includes adjustable audible and visual pulse rate, oxygen saturation, and perfusion alarms. It also includes a variety of advanced features, including low battery alarms, event markers, and real-time and print-on-demand data outputs.

	The Model 4000 System contains ISP2+ software. The improved signal processing software addresses the complaints about the effects of motion artifact on pulse oximeters by better identifying a valid pulse.
Intended Use:	The Nonin® Avant® Model 4000 Digital Pulse Oximetry System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, and infant patients. It is indicated for spot-checking and / or continuous monitoring of patients during both no motion and motion conditions, and for patients who are well or poorly perfused.
Functional and Safety Testing:	Nonin's Avant 4000 Pulse Oximetry System 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 devices.
Conclusion:	Nonin's Avant Model 4000 is substantially equivalent to the Avant® Model 4000 Pulse Oximetry System manufactured by Nonin Medical, Inc. and cleared by the FDA under K041156 on 06/09/04.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2005

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

Re: K052669
Trade/Device Name: Avant® Model 4000 Pulse Oximetry System
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 26, 2005
Received: September 30, 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.

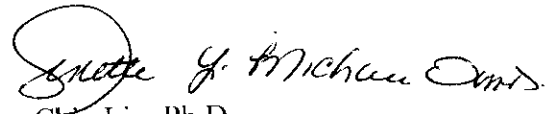
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Enclosure

Indications for Use Statement

510(K) Number: _____
(If known)

Device Name:

Avant® Model 4000 Pulse Oximetry System

Indications for Use:

The Nonin® Avant® Model 4000 Digital Pulse Oximetry System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, and infant patients. It is indicated for spot-checking and / or continuous monitoring of patients during both motion and no motion conditions, and for patients who are well or poorly perfused.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR 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)

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