JUN - 9 2004

K041156

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: April 30, 2004

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 2120 Pulse Oximeter manufactured by Nonin Medical, Inc. that was cleared by the FDA under K013319 on 1/03/02, and the Wireless Medicine LifeSync™ System (K030765).

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 is designed for spot-checking and / or continuous noninvasive measuring and displaying of functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate.

The Avant 4000 System is intended for use with adult, pediatric, and infant patients.

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, real-time and print-on-demand data outputs.

Incorporating Bluetooth® Technology in the Avant 4000 eliminates the connection from the wrist worn oximeter module to the display unit giving patients increased ability to move freely without being hindered by cables.

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.

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 2120 Pulse Oximeter manufactured by Nonin Medical, Inc. and cleared by the FDA under K013319 on 1/03/02.

Previously cleared Bluetooth predicate device: Wireless Medicine LifeSync™ System (K030765).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2004

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

Re: K041156
Trade/Device Name: Avant® Model 4000 Digital Pulse Oximetry System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 30, 2004
Received: May 3, 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) 594-4646. 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 Statement

510(K) Number: K041156

Device Name:

Nonin Medical, Inc. Avant® Model 4000

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.

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

510(k) Number: K041156

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)