K040589

JUN - 3 2004

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: May 24, 2004

Trade Name: Avant™ 9600 Pulse Oximeter

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

Product Code: 74 DQA

Predicate Device(s): The Avant™ 9600 is substantially equivalent to the Avant 2120 (K031487), which is also manufactured by Nonin Medical.

Device Description: The Avant™ 9600 Digital Pulse Oximeter is a portable tabletop device designed for continuous noninvasive measurement, display, and recording of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate using one of a range of compatible oxygen sensors. The Avant™ 9600 is intended for prescription use with adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, home care, and subacute environments. It may also be used in patient transport, sleep laboratories, and EMS environments.

The Avant™ 9600's 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™ 9600 can be powered internally with a 12 VDC 1.5A AC adapter or with an integral sealed 7.2-volt rechargeable NiMH battery pack.

The Avant™ 9600 includes adjustable audible and visual pulse rate, oxygen saturation, and perfusion alarms. It also includes a variety of advanced features, including low

	battery alarms, real-time and print-on-demand data outputs, a patient security mode, and nurse call options.
Intended Use:	The Nonin® Avant™ 9600 Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, home care, and subacute environments. It may also be used in patient transport, sleep laboratories, and EMS environments. The Avant™ 9600 is intended for continuous monitoring and / or spot-checking of patients during both no motion and motion conditions, for patients who are well or poorly perfused.
Functional and Safety Testing:	Nonin's Avant™ 9600 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:	The Avant™ 9600 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

JUN - 3 2004

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

Re: K040589
Trade/Device Name: Modification for the Avant™ Model 9600 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 11, 2004
Received: May 12, 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: 040589

Device Name:

Nonin Medical, Inc. Avant™ 9600

Indications for Use:

The Nonin® Avant™ 9600 Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, home care, and subacute environments. It may also be used in patient transport, sleep laboratories, and EMS environments. The Avant™ 9600 is intended for continuous monitoring and / or spot-checking of patients during both no motion and motion conditions, for patients who are well of poorly perfused.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K040589

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