510 (k) Summary

JUL 2 3 2003

K023044

SUBMITTER: Nonin Medical, Inc.

Address: Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Telephone: 763-553-9968

CONTACT PERSON: Richard P. Bennett, Director of Regulatory Affairs

DATE PREPARED: August 26, 2002

TRADE NAME: Nonin® Avant™, Model 9600, Pulse Oximeter
COMMON NAME: Pulse Oximeter

SUBSTANTIALLY EQUIVALENT TO:

The Nonin, Model Avant 2120 Pulse Oximeter/Non Invasive Blood Pressure (NIBP) Monitor

DESCRIPTION OF THE DEVICE:

The Model 9600 Pulse Oximeter determines arterial hemoglobin saturation (%SpO_2) by measuring absorption of red and infrared (IR) light passed through the tissue. The Model 9600 also measures pulse rate and displays the rate in beats per minute.

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 is also used in patient transport, sleep laboratories, and EMS environments. The Avant 9600 Pulse Oximeter is intended for continuous monitoring and/or spot-checking of patients.

INTENDED USE:

The Avant 9600 Pulse Oximeter is intended for continuous monitoring and/or spot-checking of patients for Oxygen saturation SpO2 and pulse rate.

SUMMARY OF TESTING:

The Model Avant 9600 Digital Pulse Oximeter has followed (where applicable) the Reviewer Guidance for Premarket Notification Submission of November of 1993, from the Anesthesiology and Respiratory Branch, Division of Cardiovascular, Respiratory and Neurological Devices. In addition, Nonin has conducted a Hazard Analysis and Risk Assessment, and developed extensive software/hardware procedures to confirm the performance of the product to the design requirements. Bench and safety testing have been done to verify the performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2003

Mr. Richard P. Bennett
Director of Regulatory Affairs
Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447

Re: K023044
Trade/Device Name: Model 9600 Avant Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 1, 2003
Received: May 2, 2003

Dear Mr. Bennett:

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,

Patricia Cucciniello /for

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number:

K023044

Device Name:

Nonin Medical Inc AVANT™, Model 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 is also used in patient transport, sleep laboratories, and EMS environments. The Avant 9600 is intended for continuous monitoring and/or spot-checking of patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K023044

Prescription Use X OR Over-The-Counter Use _____