K080255

510(k) Summary

MAY 23 2008

Submitter: Nonin Medical, Inc.

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

Date Prepared: January 31, 2008

Trade Name: Model 7500 Digital Pulse Oximeter

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

Product Code: 74 DQA

Predicate Device(s): Nonin's Model 7500 Digital Pulse Oximeter manufactured by Nonin Medical, Inc., cleared by the FDA under K071285 on 7/12/07.

Device Description: The Nonin® Model 7500 Digital Pulse Oximeter is a portable, tabletop device indicated for use in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients. It is indicated for spot-checking and / or continuous monitoring of patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.

The Model 7500 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 Model 7500 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 Model 7500 includes adjustable audible and visual pulse rate, oxygen saturation, and perfusion alarms. It also includes a variety of advanced features, including low battery alarms, sensor fault, user defined defaults, real-time data outputs, and patient security mode.

Intended Use:	The Nonin® Model 7500 Digital Pulse Oximeter is a portable, tabletop device indicated for use in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients. It is indicated for spot-checking and / or continuous monitoring of patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.
Functional and Safety Testing:	Nonin's Model 7500 Pulse Oximeter and 8000Q2 Ear Clip sensor have successfully undergone both bench and clinical testing in order to demonstrate that it meets the requirements of ISO 9919:2005 Clause 50 Accuracy of Operating Data, Clause 102 section 102.2 Labeling, and IEC 60601-1:1998 (ISO 10993-1:2003) Clause 48 Biocompatibility.
Conclusion:	The addition of Model 8000Q2 Ear Clip Sensor when used with Nonin's Model 7500 does not raise any new concerns regarding accuracy or risks when used in combination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

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

Re: K080255
Trade/Device Name: Nonin Medical, Inc. Model 7500
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 23, 2008
Received: April 24, 2008

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) 276-0115. 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 Nonin Medical, Inc. Model 7500

Indications for Use

The Nonin® Model 7500 Digital Pulse Oximeter is a portable, tabletop device indicated for use in measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients. It is indicated for spot-checking and / or continuous monitoring of patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(21 CFR 807 Subpart C)

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

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