K090807

SECTION 2. SUMMARY AND CERTIFICATION

510(k) Summary

JUN 30 2009

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: March 24, 2009

Trade Name: Model 7600 Regional Oximeter System

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

Product Code: DQA

Predicate Device(s): Nonin's Model 7600 Regional Oximeter System is substantially equivalent to the INVOS® Model 5100 Cerebral Oximeter manufactured by Somanetics Corporation that was cleared by the FDA under K001842 on 9/15/00.

Device Description: Nonin's® Model 7600 non-invasive Regional Oximeter System continuously monitors and records the mixed arterial/venous blood oxygen levels through non-invasive near-infrared spectroscopy sensors placed on the patient's forehead.

The stand-alone system is comprised of three subsystems; sensor, patient oximetry device (Pod) and display unit. The sensor allows light absorption measurements at various wavelengths in the near-infrared spectrum (approximately 700 to 900 nanometers). The sensor is approximately 1.5 by 3 inches.

The sensors plug into the patient oximetry device (Pod) which controls the light emitted from the sensor LEDs and measures the light returning to the sensor photodiodes. From these measurements, the Pod determines specific absorption values and calculates the mixed arterial/venous oxygen saturation values. The Pods then communicate the cerebral oxygen

saturation readings and other data to the display unit.

The display unit displays real-time cerebral oximetry trend data. It is a battery-backed, mains powered device equipped with audio and visual alarm indicators. Real-time data and playback output is accomplished through a Bluetooth transceiver module.

Intended Use:

Nonin's stand-alone non-invasive Model 7600 Regional Oximeter System is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 88 pounds (40 kilograms). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Functional and Safety Testing:

Nonin's Model 7600 Regional Oximeter System has successfully undergone both laboratory and clinical testing in order to ensure that it has appropriate functional features and is substantially equivalent to the predicate device.

Conclusion:

Nonin's Model 7600 Regional Oximeter System is substantially equivalent to the INVOS® Model 5100 Cerebral Oximeter manufactured by Somanetics Corporation and cleared by the FDA under K001842 on 9/15/00.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Nonin Medical, Inc.
c/o Lori Roth RN, BSN
Clinical/Regulatory Specialist
13700 1st Avenue North
Plymouth, MN 55441-5443

Re: K090807
Trade/Device Name: Model 7600 Regional Oximeter System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: June 2, 2009
Received: June 3, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K090807

Device Name:

Nonin Medical, Inc. Model 7600 Regional Oximeter System

Indications for Use:

Nonin's stand-alone non-invasive Model 7600 Regional Oximeter System is intended for use as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood underneath the sensor. It is intended for spot-checking or continuous monitoring of adult or pediatric patients weighing greater than 88 pounds (40 kilograms). It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care and mobile environments.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

M L B Nicholas

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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