JAN 1 1 2006 K053130

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: Nonin Medical, Inc.

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

Date Prepared: November 4, 2005

Trade Name: Onyx® II Model 9550 Finger Pulse Oximeter

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

Product Code: 74 DQA

Predicate Device(s): Nonin's Onyx® II Model 9550 is substantially equivalent to the Onyx® II Model 9550 Finger Pulse Oximeter manufactured by Nonin Medical, Inc. that was cleared by the FDA under K051107 on 06/01/05.

Device Description: The Onyx® II Model 9550 is a small, lightweight, portable, finger pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.

Light omitting diodes (LEDs) are contained within the sensor along with the photo detector, which is on the opposite side of the probe from the LEDs. The SpO_2 and heart rate are displayed on the LED digital displays contained within the finger clip sensor. A tricolor LED display provides a visual indication of the pulse quality signal, while blinking at the corresponding pulse rate. This display changes colors to alert you to changes in pulse quality that may affect the readings: green indicates a good pulse quality signal, yellow indicates a marginal pulse quality, and red indicates as inadequate pulse signal. All

	associated electronics and the microprocessor are within the sensor, which is activated by inserting a patient's finger. This allows the power to be applied to all the internal circuitry upon activation. The device is intended for spot-checking adult and pediatric patients who are well or poorly perfused.
Intended Use:	The Nonin® Onyx® II Model 9550 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 – 2.5 cm) thick. The index finger is the recommended site.
Functional and Safety Testing:	Nonin's Model 9550 Finger Pulse Oximeter has successfully undergone bench testing in order to demonstrate that it has appropriate functional features and is substantially equivalent to the predicate device.
Conclusion:	Nonin's Model 9550 is substantially equivalent to the Model 9550 Finger Pulse Oximeter manufactured by Nonin Medical, Inc. and cleared by the FDA under K051107 on 06/01/05.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2006

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

Re: K053130
Trade/Device Name: Onyx® II Model 9550 Finger Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 4, 2005
Received: November 8, 2005

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) 276-0120. 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:

Onyx® II Model 9550 Finger Pulse Oximeter

Indications for Use:

The Nonin® Onyx® II Model 9550 Finger Pulse Oximeter is a small, lightweight, portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of patients who are well or poorly perfused. It is intended for spot-checking of adult and pediatric patients on fingers (other than the thumb) between 0.3 – 1.0 inch (0.8 - 2.5 cm) thick. The index finger is the recommended site.

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)

(Division Sign-Off)
Division of [illegible] General Hospital,
Infection Control, Dental Devices
510(k) Number K053130