

JUN 1 - 2005

K051107

Attachment 7

510(k) Summary

Submitter: Nonin Medical, Inc.

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

Date Prepared: April 28, 2005

Trade Name: Model 9550 Onyx® II Finger Pulse Oximeter

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

Product Code: 74 DQA

Predicate Device(s): The predicate device is the Model 9500 Onyx® Finger Pulse Oximeter, K001085, cleared on May 1, 2000.

Device Description: The Model 9550 Onyx® II is a small, lightweight, portable, finger pulse oximeter that displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO₂) 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 emitting 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 SpO₂ 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.

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 (SpO₂) and pulse rate. 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 Onyx® II Model 9550 Finger Pulse Oximeter has successfully undergone both bench and human testing to support the determination of substantial equivalence. Human oxygenation evaluations were conducted to confirm conformance to accuracy and precision specifications.

Conclusion:

Nonin's Onyx® II Model 9550 Finger Pulse Oximeter is substantially equivalent to the predicate devices in terms of accuracy, functional design and principles of operation. Performance test results do not raise new questions of safety and effectiveness when compare to the legally marketed devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K051107
Trade/Device Name: Onyx® II Model 9550
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 28, 2005
Received: May 2, 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

Attachment 2

Indications for Use Statement

510(k)

Number

(if known)

K051107

Device Name

Nonin Medical, Inc. Onyx® II Model 9550

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 (SpO₂) and pulse rate. 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.

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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