AUG 12 1999

K982969

510(k) Summary

SUBMITTER: **Nonin Medical, Inc.**

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

Telephone: 612-553-9968

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

DATE PREPARED: **August 21, 1998**

TRADE NAME: **NONIN® Pulse Oximeter and Carbon Dioxide Detector**
COMMON NAME: **Pulse oximeter and carbon dioxide detector**

SUBSTANTIALLY EQUIVALENT TO:

The NONIN Pulse Oximeter and Carbon Dioxide Detector are substantially equivalent to: **(1)** The pulse oximeter segment is substantially equivalent to the NONIN Models 8500/8500A Pulse Oximeters [510(k)s 893221/945290]. **(2)** The Carbon Dioxide [CO_2] Detector segment is substantially equivalent to the Nellcor Stat Cap Model N-60B [510(k) 915494]. **(3)** The NONIN Model 9843, 9845, and 9847 Pulse Oximeter and CO_2 Detector is substantially equivalent to the two-parameter Spegas MicroCap/NPB-75 [K964239] which likewise functions as a dual function instrument displaying CO_2 and SpO_2.

DESCRIPTION of the DEVICE:

The **NONIN® Pulse Oximeter and Carbon Dioxide Detector** (Model 9840-Series), is a hand-held, battery-operated, noninvasive monitoring device that has visual and audible indicators for tracking patient status. Each Pulse Oximeter and Carbon Dioxide Detector model performs similar basic functions, but each model has been customized to meet the needs of different demands placed upon the health care professional.

Each model of the **NONIN® Models 9840-Series** has informational tones, (along with visible indicators) to alert healthcare providers to patient conditions. However only

Model 9845 and **Model 9847** have an high priority "absence-of-breath" (apnea) audible alarm. The **Model 9843** indicates that there is an "absence-of breath" by the cessation of the information tone, the breath-beep indicator.

Model 9845 and **Model 9847** have medium priority (equipment) alarm that either indicates that the batteries have reached a critically low power state or that a CO_2 sensor alarm condition is occurring. The **Model 9843** indicates a low battery condition by an illuminated low battery indicator.

Model 9847 has a high priority (patient) alarm to alert the healthcare provider to "absence of breath" (apnea), a high or low oxygen saturation, a high or low pulse rate or inadequate pulse quality conditions.

Audible alarms can be "permanently" or "temporarily" disabled using the audible alarm disable switch on **Model 9845** and **Model 9847**.

INDICATIONS FOR USE:

The **NONIN® Pulse Oximeter and Carbon Dioxide Detector (Model 9840-Series)** is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and approximate carbon dioxide (CO_2) changes in the airway of intubated patients. These functions may be used separately or simultaneously.

SUMMARY of TESTING:

The Model 9840-Series testing has followed (where applicable), the Reviewer Guidance for Premarket Notification Submission of November 1993, from the Anesthesiology and Respiratory Branch, Division of Cardiovascular, Respiratory and neurological Devices. In addition, NONIN Medical, Inc. has evaluated these models for conformance with referenced voluntary international standards. NONIN Medical, Inc. has conducted an extensive Hazard Analysis and Risk Assessment, and developed extensive software/hardware verification and validation procedures to confirm the performance of the product to design requirements. Field evaluations have confirmed the accuracy of the Carbon Dioxide Detector in a controlled clinical environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Mr. Richard P. Bennett
Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Re: K982969
NONIN Pulse Oximeter and Carbon Dioxide Detectors: Model 9840-Series
Regulatory Class: II (two)
Product Code: 73 CCK and 74 DQA
Dated: July 3, 1999
Received: July 8, 1999

Dear Mr. Bennett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K982969

Device Name: **NONIN® Pulse Oximeter and Carbon Dioxide Detector**

Indications for Use:

The **NONIN® Pulse Oximeter and Carbon Dioxide Detector (Model 9840-Series)** is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and approximate carbon dioxide (CO_2) changes in the airway of intubated patients. These functions may be used separately or simultaneously.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

Joanne A. Weston-Hewson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____