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510(k) Summary

3 October 2001

JAN 0 3 2002

(1) Submitter information

Name: Nonin Medical, Inc.

Address: 2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Telephone: 763-553-9968

Registration Number: 2183646

Contact person: Richard P. Bennett (Official Correspondent)

Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755
Tel: 763-577-3166
Fax: 763-553-7807

Date prepared: 1 October 2001

(2) Name of Device

Device Trade Name: NONIN® Model 2120 Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor

Device Common / Classification Name: Pulse Oximeter with Noninvasive Blood Pressure

Device Class: Class II; 74 DQA, 870.2700; 74 DXN, 870.1130. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Pulse Oximeters.

(3) Legally-marketed predicate devices

MTS Option for the ESCORT® II Monitor, K970763, made by Medical Data Electronics, clearance date, July 14, 1997.

Model 9303 Neonatal / Adult Vital Signs Monitor, K982776, made by CAS Medical Systems, Inc., clearance date, November 2, 1998.

OSCAR 2, K003004, made by SunTech Medical Instruments, clearance date, October 25, 2000.

The NONIN® Model 2120 Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor is substantially equivalent to these devices.

(4) Description

The Model 2120 combines Pulse Oximetry and NIBP, utilizing the same fundamental scientific technology and intended use as the predicate devices.

Pulse Oximetry

The NONIN® Model 2120 Finger Pulse Oximeter passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial blood pressure pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin from this color difference by measuring the ratio of absorbed red and infrared light as the blood volume fluctuates with each heart beat.

Blood Pressure Measurement

The NONIN® Model 2120 NIBP uses an oscillometric step deflate technique to determine blood pressure. An internal electric pump is used to inflate the cuff, and deflation is controlled by two valves. During cuff deflation, small cuff pressure changes (resulting from arterial blood pressure pulses) are analyzed by the microprocessor, in order to determine the blood pressure. The Model 2120 has the ability to make blood pressure measurements at predetermined intervals or on demand. The Model 2120 has a Memory playback feature, allowing stored data to be transferred to a computer through data acquisition software for analysis.

(5) Intended Use

Indications for Use:

The NONIN® Model 2120 Pulse Oximeter and NIBP Monitor is a portable device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and blood pressure of adult and pediatric patients in hospitals, medical facilities, and subacute environments. The Model 2120 is intended for spot-checking and / or continuous monitoring of patients. Its functions may be used separately or simultaneously.

Pulse Oximeter Intended Use:

The pulse oximeter is intended for noninvasively monitoring the oxygen saturation and pulse rate of adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, and subacute environments. It may also be used for spot-checking and / or continuous monitoring of patients.

Blood Pressure Monitor Intended Use:

The blood pressure monitor is intended for noninvasively monitoring the blood pressure of adult and pediatric patients in hospitals, medical facilities, and subacute environments. *The blood pressure monitor is not intended for use with neonates.* It is intended for attended care and may be used for spot-checking.

The Model 2120 should be used for patients with arm circumferences of 18-42 cm.

(6) Testing and Validations

(a) Non-clinical Tests

The Model 2120 has passed the following tests and validations:

- AAMI SP10 Electronic or Automated sphygmomanometers.
- EN60601-1 Medical Electrical Equipment - General requirements for Safety
- EN60601-2-30 Medical Electrical Equipment – Specific requirements for Blood Pressure monitors
- IEC 601-1-2 Electromagnetic Compatibility
- EN1060-1 Non-invasive sphygmomanometers - General Requirements
- EN1060-3 Non-invasive sphygmomanometers- Supplementary requirements for electro-mechanical blood pressure measuring systems

(b) Clinical tests

Since the Model 2120 NIBP uses the same technology as existing devices, clinical tests are not required. However, the supplier of the NIBP module, SunTech Medical Instruments, performed clinical testing according to AAMI SP10, in which the system was compared to manual readings on patients according to section 4.4.2 of AAMI SP10, and it has satisfactorily passed this test.

(7) Conclusion

The NONIN® Model 2120 Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor is equivalent in safety and efficacy to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 3 2002

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

Re: K013319
Trade Name: Nonin Model 2120 Pulse Oximeter and Noninvasive Blood Pressure Monitor
Regulation Number: 21 CFR 870.2700 and 870.1130
Regulation Name: Oximeter and Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: 74 DQA & 74 DXN
Dated: October 3, 2001
Received: October 5, 2001

Dear Mr. Bennett:

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.

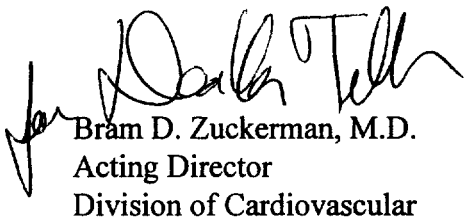
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013319

~~Special~~ 510(k): Device Modification

JAN 0 3 2002

Indications for Use Form

510(k) Number (if known):

Device Name: NONIN® Model 2120 Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013319