Special 510(k): Device Modification

MAR 2 2 2004

Attachment 4

510(k) Summary

Nonin Medical, Inc.

Model 2120 Avant™ Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor

510(k) Summary

9 May 2003

(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:	9 May 2003

(2) Name of Device

Device Trade Name:	NONIN® Model Avant™ 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

Model Avant™ 2120 Pulse Oximeter and NIBP, K013319, clearance date January 3, 2002, by Nonin Medical, Inc.

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Model N-395 Pulse Oximeter with Extension of Motion Performance Claims to cover three additional oximetry sensors, K993637, clearance date November 24, 1999 made by Nellcor Puritan Bennett.

Masimo SET® Radical Pulse Oximeter, K013792, clearance date December 11, 2001, made by Masimo Corporation.

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

(4) Description

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

Pulse Oximetry

The NONIN® Model Avant™ 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 Avant™ 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 Avant™ 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 Avant™ 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 pulse oximeter is intended for spot-checking and / or continuous monitoring of patients during both no motion and motion conditions, for patients who are well or poorly perfused. Its functions may be used separately or simultaneously.

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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. The Model 2120 is intended for spot-checking and / or continuous monitoring of patients during both no motion and motion conditions, for patients who are well or poorly perfused.

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) Conclusion

The NONIN® Model Avant™ 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

MAR 2 2 2004

Nonin Medical, Inc.
c/o Mr. John R. Dalpee
Director of Regulatory Affairs
2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Re: K031487
Trade Name: Model 2120 Avant™ Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: February 16, 2004
Received: February 19, 2004

Dear Mr. Dalpee:

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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

Donna R. Vachner

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

Enclosure

K031487/S2

Indications for Use

510(K) Number: K031487

Device Name: Model 2120 Avant™ Pulse Oximeter and Noninvasive Blood Pressure (NIBP) Monitor

Indications for Use:

The Nonin® Model Avant™ 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 during both no motion and motion conditions, for patients who are well or poorly perfused. Its functions may be used separately or simultaneously.

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031487