MAY - 6 2004

K033307

SECTION 2. Summary and Certification

A. 510(K) Summary

Submitter: Nonin Medical, Inc.

Contact Person:
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Date Prepared: 10 October, 03

Trade Name: nVISION® Data Management Software (K033307). Class II, 21 CRF 870.2700.

Classification Name And Number: Pulse Oximeter Data Management Software

Product Code: DQA

Predicate Devices: nVISION® Data Management Software is substantially equivalent to Respironics' Profox Software (K001708) and Nellcor's Score Software (K961450).

Device Description: nVISION® Data Management Software (nVISION) is an optional accessory for compatible Nonin oximeters with memory playback. nVISION® software is indicated for use with the following Nonin oximeters: 9700, 3100, 9600, 2120, 2500, 8500, 8600, 8800, and 9840. nVISION® software runs on a personal computer and provides a graphical display of downloaded oximetry data for review and interpretation by a clinician. This software also allows oximetry data and patient information to be saved in a "library" for future retrieval and analysis. The healthcare professional using nVISION® software is solely responsible for selecting the analysis criteria used to calculate summary statistics included in the reports. nVISION® software is an adjunct system requiring human interpretation of results; it does not suggest a course of treatment or generate a diagnosis.

Intended Use:

nVISION® Data Management Software (nVISION) is an optional accessory for compatible Nonin oximeters with memory playback. nVISION® software is indicated for use with the following Nonin oximeters: 9700, 3100, 9600, 2120, 2500, 8500, 8600, 8800, and 9840. It is intended for use by healthcare professionals when (1) transferring data from pulse oximeters to computers in order to maintain individual records of pulse oximetry data, (2) reviewing that data according to user-selected parameters, and (3) generating reports.

Functional and Safety Testing:

Representative samples of nVISION® software successfully underwent performance testing to demonstrate appropriate functional characteristics.

Conclusion:

nVISION® Data Management Software is substantially equivalent to Respironics' Profox Software (K001708) and Nellcor's Score Software (K961450).

This conclusion is based on the fact that nVISION® software is equivalent to the predicate devices in terms of functional design, indications for use, principles of operation, software platform, and hardware requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2004

John R. Dalpee
Director of Regulatory Affairs
Nonin Medical, Incoporated
2605 Fernbrook Lane, North
Minneapolis, MN 55447-4755

Re: K033307
Trade/Device Name: nVision Data Management Software
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 12, 2004
Received: March 15, 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) 594-4646. 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,

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 Page

510(K) Number : 033307

Device Name: nVISION® Data Management Software

Indications for Use:

nVISION® Data Management Software (nVISION) is an optional accessory for compatible Nonin oximeters with memory playback. nVISION is indicated for use with the following Nonin oximeters: 9700, 3100, 9600, 2120, 2500, 8500, 8600, 8800, and 9840. It is intended for use by healthcare professionals when (1) transferring data from pulse oximeters to computers in order to maintain individual records of pulse oximetry data, (2) reviewing that data according to user-selected parameters, and (3) generating reports.

Prescription Use X And/Or Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 033307