K092678

510(k) Summary

OCT - 1 2009

Submitter: Nonin Medical, Inc.

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

Date Prepared: August 31, 2009

Trade Name: Data Management Software

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

Predicate Device(s): Nonin's nVISION Data Management Software (K033307) cleared on 05/06/2004.

Device Description: eVISION® Data Management Software (eVISION) is an optional accessory for use with the Model 7600 Regional Oximeter System to display and summarize downloaded patient regional oxygen saturation (rSO_2) data on a personal computer. Data can be displayed as data graphs and/or statistics for review and interpretation by a clinician. Data is obtained from the Model 7600 via Bluetooth® connection provided by the host computer on which eVISION is installed. The software also allows regional oximetry data and patient information to be saved in a "library" for future retrieval and analysis. The clinicain using eVISION® software is solely responsible for selecting the analysis criteria used to calculate summary statistics included in the reports. eVISION® software is an adjunct system requiring clinician interpretation of results; it does not suggest a course of treatment or generate a diagnosis.

Intended Use:	eVISION® Data Management Software (eVISION) is an optional accessory for use with Nonin's Model 7600 Regional Oximeter System. It is intended for use by healthcare professionals when 1) transferring data from the Model 7600 to a computer in order to maintain individual records of regional oximetry data, 2) reviewing data according to user-selected parameters, and 3) generating reports.
Functional and Safety Testing:	The Risk Management process is used to assess the safety of the device; no new risks were identified with the modification to the eVISION Data Management Software. Software Verification and Validation was completed to verify the performance, functionality, and features of eVISION.
Conclusion:	This submission demonstrates that the modified eVISION Data Management Software is substantially equivalent to Nonin's nVISION Data Management Software (K033307) cleared on 05/06/2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Nonin Medical, Inc.
c/o Ms. Lori M. Roth
13700 1st Ave. North,
Plymouth, Minnesota 55441-5443

OCT - 1 2009

Re: K092678
Trade/Device Name: eVISION Data Management Software
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 31, 2009
Received: September 1, 2009

Dear Ms. Lori:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Ms. Lori M. Roth

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K092678

Device Name Nonin Medical, Inc. eVISION® Data Management Software

Indications for Use:

eVISION® Data Management Software (eVISION) is an optional accessory for use with Nonin's Model 7600 Regional Oximeter System. It is intended for use by healthcare professionals when 1) transferring data from the Model 7600 to a computer in order to maintain individual records of regional oximetry data, 2) reviewing data according to user-selected parameters, and 3) generating reports.

Prescription Use ____X_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092678