



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Natus Medical Incorporated
c/o Ms. Goldy Singh
Director of Quality and Regulatory
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

APR 19 2011

Re: K090277

Trade/Device Name: Natus SleepWorks
Regulation Number: 21 CFR 882.1400
Regulation Name: Automatic Event Detection Software for Polysomnograph with
Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: October 1, 2010
Received: November 30, 2010

Dear Ms. Singh:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


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.

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" (21 CFR 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,


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

510(k) Number (if known): K090277

Device Name: Natus SleepWorks

Indications For Use:

The Sleepworks software works in conjunction with Connex, Trex or Netlink amplifiers intended for polysomnography studies. The software allows recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various sleep disorders and sleep related respiratory disorders.

The Sleepworks allows:

- Automated analysis of physiological signals that is intended for use only in adults.
- An optional Audio / visual alert for user defined threshold on calibrated DC input. These alerts are not intended for use as life support such as vital signs monitoring or continuous medical surveillance in intensive care units.
- Sleep report templates are provided which summarize recorded and scored sleep data using simple measures including count, average, maximum and minimum values as well as data ranges for trended values;

SleepWorks software does not provide any diagnostic conclusion about the patient's condition and is intended to be used only by qualified and trained medical practitioners, in research and clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 SKO

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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