510(K) Summary

AUG 2 9 2011

Natus Medical Incorporated
DBA Excel-Tech Ltd.
2568 Bristol Circle,
Oakville, Ontario, L6H 5S1

Date: Aug 11, 2011

Name of the device – Harmonie System

Common Name – Electroencephalograph and Polysomnograph

Classification name – EEG/PSG Monitoring (21 CFR 882.1400 Product Code GWQ)

The Harmonie System is substantially equivalent to K010728 – Harmonie Schwarzer EEG System and K053606 – BE Plus / AURA-LTM64 Amplifier.

Device Description:

The Harmonie System is a data acquisition device that can record up to 128 channels of EEG and PSG signals at sample rates ranging from 200Hz to 2000Hz per channel according to the specifications of each model. EEG and PSG signals are amplified, filtered and digitized. A Photic Stimulator is optionally provided with the system. The system can also concurrently record synchronized digital patient video, through an optional MPEG4 encoder card and the DV software module. The digital data (EEG and digital video) is stored on the computer workstation's hard disk for review and analysis, either during or after a recording session.

Following is the functional description of various Harmonie models:

1. Harmonie System with DUO Recorder

   This is a basic EEG recording system, typically used for routine EEG examination. The DUO recorder is a 20-bit, 44-channel amplifier with user programmable filters, automatic anti-aliasing and sampling rates of up to 2,000 Hz. All components are mounted on a robust enclosed cart, which can accommodate a Photic Stimulator and various models of CCTV cameras, as accessories. The system includes Harmonie EEG software that allows acquisition, display, review, analysis and archiving of EEG data locally or at a remote station.

2. Harmonie-S System with DUO Recorder

   The Harmonie-S system uses same DUO recorder described above but uses PSG software to record sleep studies. It includes optionally digital video recording. The amplifier and video camera are placed in the room. The computer and monitor are placed in an observation room where the PSG technologist works. The software includes the Harmonie EEG and the PSG modules. The

PSG module is designed specifically for the visualization and scoring of variables commonly used in sleep studies, such as the EEG, EMG, EKG, oxygen saturation, body position , eye movements and respiration signals. The system allows performing the main functions of a sleep study: sleep staging, manual event marking, displaying graphs of sleep stages and events, and various sleep report generation.

3. MESA II System with DUO Recorder

MESA-II is a portable system suitable for EEG examinations, also using the DUO EEG amplifier. It offers the full functionality of the standard Harmonie system, but with a laptop computer and other components mounted on a cart with a smaller foot-print, which enables EEG examinations to be performed in space-limited environments. The cart can accommodate a Photic Stimulator and various models of CCTV cameras, as accessories. The system includes Harmonie EEG software that allows acquisition, display, review, analysis and archiving of EEG data locally or at a remote station.

4. Vita ICU System with DUO Recorder

The Vita ICU system is an EEG recording system designed to facilitate EEG recordings in the ICU, although it can also be used as a routine EEG system. It includes optionally digital video recording. The Vita ICU system is composed of a panel PC (computer and monitor in the same physical entity), including a touch-screen monitor, and is mounted on small footprint cart. It includes the Harmonie EEG software as well as software specific for this application (the Vita ICU software). The Vita ICU software includes a touch-screen interface to facilitate user-interaction with the device.

5. Harmonie-E System with eAmp Recorder

The Harmonie-E system with eAmp recorder is an EEG recording system designed for LTM particularly in the context of the evaluation of patients with epilepsy. The eAmp is an IP-enabled amplifier with the capability to acquire data for up to 128 channels (by combining two 64-channel units). It includes programmable filters from 0.1 to 500Hz and sampling rates up to 2,000Hz that allow measurement of higher frequency EEG. The system includes digital video recording. The amplifier and video camera are placed in the room and the recording computer and monitor and placed in a control room. The system includes Harmonie EEG software that allows acquisition, display, review, analysis and archiving of EEG data locally or at a remote station. The Harmonie-E module for the automatic marking of EEG events of interest, i.e. spike patterns and seizure patterns. This post-hock review marking facilitates the review of the long EEG recordings.

6. Harmonie-E System with EEG64 Recorder

The Harmonie-E system with Schwarzer EEG64 recorder is an EEG recording system designed for LTM particularly in the context of the evaluation of patients with epilepsy. The Schwarzer EEG64 amplifier is equivalent to eAmp with slightly different filtering characteristics than the eAMP amplifier. The system includes Harmonie EEG software that allows acquisition, display, review, analysis and archiving of EEG data locally or at a remote station.

Intended Use:

The Harmonie System is indicated for the acquisition, display, review, analysis and archiving of physiological signals including patient video obtained during routine EEG examinations, Long-Term Monitoring in Epilepsy (LTM) and Sleep Studies (polysomnography or PSG) in patients of all ages.

The seizure detection component of the software is intended for post-hoc review for marking sections of the EEG that may correspond to electrographic seizures in adults only. The Burst-Suppression component is intended to be used for the quantification and recognition (mark) of sections of the EEG and PSG that may contain patterns of interest. The seizure detection component and Burst-Suppression Module are for use in adults only.

The Harmonie software is not intended to replace conventional devices or methods used for sleep monitoring in critical care or intra-operative settings.

In no way are any of the system functions represented as being in and of themselves diagnostic. The system requires competent user input, and its output must be reviewed and interpreted by a physician or other trained health care professional who will exercise professional judgment in using this information.

Performance Data

Bench testing and verification and validation activities were performed to establish the performance, reliability and the functionality of the Harmonie system. Pass/Fail criteria were established based on the published specifications of applicable safety standards, predicate and the current device.

Conclusion

The conclusion drawn from the test results and review of scientific literatures support is that the device and the indications for use are substantially equivalent to the predicate device and do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Division, Natus Medical Incorporated
c/o Ms. Goldy Singh
Director of Quality & Regulatory
2568 Bristol Circle,
Oakville, Ontario
Canada L6H 5S1

AUG 29 2011

Re: K083577
Trade/Device Name: Harmonie System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: April 8, 2011
Received: April 8, 2011

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" (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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083577

Device Name: Harmonie System

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

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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K083577