K023536

V. 510(k) Summary

Safety and effectiveness information concerning this device is summarized below. Because this is not a Class III device, the special certification defined in this section is not required.

JAN 1 5 2003

Submitted by: Neuroscan
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Contact Person: Elvira Garcia

Date Prepared: October 9, 2002

Proprietary Name: Nuamps®

Common Name: Electroencephalograph (EEG)

Classification Name: Electroencephalograph (GWQ), OLT

Device Classification
Class II: 21 CFR § 882.1400 Electroencephalograph

Predicate Device: SCAN LT
510(k) # K001564

Description of the Device: The Neuroscan Nuamps® is a 40-channel EEG amplifier capable of direct current (DC) recording, including signal amplification, analog-to-digital conversion, and filtering. Nuamps® permits high-speed simultaneous sampling, acquisition and transfer of data host computer that controls, displays, and stores the acquired data. Nuamps®'s software routines separately control each channel and perform real-time digital filtering. Nuamps® software measures and analyzes EEG signals and performs analysis of complete data sets, calculates compressed spectrum arrays (CSA), and presents results as annotated signal plots or topographic/tomographic maps in real-time two or three-dimensional (2/3-D) context. Nuamps® is optically isolated and transformers are available for line voltages of 100, 120, 230, VAC.

The Neuroscan Nuamps® systems works in the same manner as the approved and predicate device, and:

- permits 1 to 40 channels configuration, and
- simplifies the acquisition, recording and analysis of the data generated in high-resolution

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The Neuroscan SCAN LT was slightly modified to make the Neuroscan Nuamps. The modification does not affect the safety or effectiveness of the device. The modification consisted of a hardware change. We added a 12-bit trigger board that adds timing information on stimulus presentation to the EEG data collected by the amplifier.

Statement of Indications For Use:

The Neuroscan Nuamps® system is intended for the measuring, recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical setting for EEG.

Patient Population: Adults, children and infants

510(k) Summary of Non-Clinical Testing

The following is a list of test performed on the Neuroscan Nuamps® system. These tests demonstrate that the performance of the system is equivalent to that of the predicate devices in the terms of safety and effectiveness, and that the additional features provide utility and product performance which exceed that of the predicate devices. All tests were completed satisfactorily without adverse report.

The Neuroscan Nuamps® system was designed and is manufactured to comply with:

- IEC-60601-1
- IEC-60601-1-1
- IEC-60601-1-1-2
- IEC-60601-1-1-4
- IEC-60601-1-2-26
- EN46001
- EN ISO9001:2000
- MDD 93/42/EEC
- AAMI EC53-1995
- CDRH Guidance Document on the "Performance Standard for Electrode Lead Wire and Patient Cables," March 9, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Neuroscan
Elvira Garcia
Quality Assurance Manager
7850 Paseo del Norte, Suite 101
El Paso, Texas 79912

Re: K023536
Trade/Device Name: NuAmps
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, GWQ
Dated (Date on orig SE ltr): October 9, 2002
Received (Date on orig SE ltr): October 21, 2002

APR - 9 2012

Dear Ms. Garcia:

This letter corrects our substantially equivalent letter of January 15, 2003.

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,

Keoia 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

IV. Statement of Indications for Use

Applicant: Neuroscan
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51(k) Number: K023536

Device Name: Neuroscan Nuamps®

Indications For Use: The Neuroscan Nuamps® system is intended for the measuring recording and analysis of the electrical activity of a patient's brain and/or through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical settings for EEG. The system is intended for the EEG and long/middle-latency EP registration in the research environment

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

Concurrence of CDRH, Office of device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023536

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(Per 21 CFR 801.109)

(Optional Format 1-2-96)