K023771

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.

Submitted by: Neuroscan
7850 Paseo Del Norte, Suite 101
El Paso, TX 79912
Phone: 915-845-5600 ext 217
Fax: 915-845-2965

FEB 0 6 2003

Contact Person: Elvira Garcia

Date Prepared: October 30, 2002

Proprietary Name: SynAmps²

Common Name: Electroencephalograph (EEG)

Classification Name: GWQ, GWP, GWF, GWE, GWJ

Device Classification
Class II: 21 CFR § 882.1400 Electroencephalograph

Predicate Device: SynAmps
510(k) # K001324

Description of the Device:

The SynAmps²® Amplifier System is an EEG/ERP/EP amplifier and data acquisition system. The amplifier and data acquisition electronics are housed in a small enclosure (Headbox) placed near the patient, and into which individual electrodes, collections of electrodes, may be connected. Additionally a high density electrode cap connector is provided on the Headbox. The Headbox also contains a connector for the interconnect cable to the System Unit.

The System Unit is slightly larger than the Headbox and serves as an interface between up to four Headboxes and the host computer.

The system operates under the software control of a host computer over a USB 2.0 interface. Data flows from the SynAmps² amplifier over this interface. Multiple System Units may be connected to the host, to obtain systems of up to 512 channels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2003

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

Re: K023771
Trade/Device Name: SynAmps2
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: November 6, 2002
Received: November 12, 2002

Dear Ms. Garcia:

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) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Statement of Indications for Use

Applicant: Neuroscan
7850 Paseo Del Norte, Suite 101
El Paso, TX 79912
Phone: 915-845-5600 ext. 217
Fax: 915-845-2965

51(k) Number: K023771

Device Name: Neuroscan SynAmps²

Indications For Use: The Neuroscan SynAmps² system is intended for measuring recording 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/short-latency EP registration in the research environment. The system is intended to be used by qualified/trained EEG technologists and/or physicians. The data acquired must be interpreted by qualified physicians.

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

Concurrence of CDRH, Office of device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K023771

(Per 21 CFR 801.109)