JUN - 1 2004

K041198

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham, Official Corresondent
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Carri Graham

Date: May 5, 2004

807.92(a)(2)

Trade Name: Nic36 Amplifier

Common Name: Physiological Signal Amplifier

Classification Name(s): Physiological Signal Amplifier

Classification Number: 84GWL

807.92(a)(3)

Predicate Device(s)

EB Neuro, S.p.A.	Mizar Amplifier	K003154

Additional Substantial Equivalence Information is provided in the following Technological Characteristics Table.

807.92 (a)(4)

Device Description

The Nic36 Amplifer is a fully programmable system which provides a total of 36 analog input channels each of which can be configured, amplified and converted to digital form (analog to digital conversion). The amplifier receives its power from a dedicated AC/DC adapter, meeting the IEC 601-1 requirements, which feeds a +15VDC. Internally, the +15VDC is further isolated by a dedicated DC/DC CF type converter.

The Nic36 Amplifier is intended to be used to amplify and filter bioelectric signals captured via a lead or transducer on the surface of the human body. It captures the data, converts it into a digital form and passes it on to a host computer running appropriate amplification software. Typical fields of application will be: Electroencephalograph (EEG), Evoked Potentials (EP), Electromyography (EMG), Polysomnography (Sleep Analysis) and General Polygraphy.

The Nic36 Amplifier does not contain a Pulse Oximeter module.

The host computer must use one of the following Operating Systems: Microsoft Windows 98, Microsoft Windows NT or Microsoft Windows XP.

The Nic36 Amplifier system consists of three interconnected units: the amplifier box, the PC interface (BE Net/NicNet) and the AC/DC adapter; optionally the system may be completed by a led visual stimulator.

807.92(a)(5)

Intended Use(s)

The Nic36 Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

807.92(a)(6)

Technological Characteristics

Item	EB Neuro MIZAR Amplifier K003154	EB Neuro Nic36 Amplifier This Submission
Intended Use	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations
EEG/Polygraphic channel	32/40 (64/96/128 with expansion boards)	36 monopolar fixed - (no expansion boards)
DC channel	32/40	4
A/D conversion	16 bit Sigma-Delta A/D effectively transferred to host	16 bit SAR effectively transferred to host
Sampling rate	User selectable (128, 256, 512 . . .up to 32 KHz/Channel	User selectable (128, 256, 512 . . . up to 8192 Hz/Channel)
CMRR	>100dB	>100dB
Noise	< 1.5 μVpp	<0.5 μVrms(AC) <7 μVrms(DC)
Power Supply	External IEC 601-1 mains adapter Internal batteries (optional)	External IEC 601-1 mains adapter
Internal Storage	N/A	N/A
Amplifier – PC Interface	PCMCIA or BE Net	PCMCIA (NicPCMCIA) or BE Net (NicNet)
Other Interfaces	128x64 graph LCD display 5 push buttons	Power on LED / LED matrix Ohm Meter
Use standard sensors and electrodes	Yes (electrodes and sensors are not included with the Amplifer)	Yes (electrodes and sensors are not included with the Amplifier)
Dimension	250 (L) x 170 (W) x 65 (h) (mm)	203 (L) x 135 (W) x 38 (H) (mm)
Weight	1.5 Kg	0.55 Kg
Isolation	Fiber optic link Patient isolation BF type	Fiber optic link Patient isolation CF type

Safety Standards	IEC 601-1 IEC 601-1-2 IEC 601-2-26 IEC 601-1-4	IEC 601-1 IEC 601-1-2 IEC 601-2-26 IEC 601-1-4
System Components	Amplifier Head box AC/DC Adapter PCMCIA or BE Net Interfaces DC Input box (optional) LED Flash stimulator (optional)	Amplifier AC/DC Adapter PCMCIA (NicPCMCIA) or BE Net (NicNet) Interface DC Input box (NicDCIN) (optional) LED Flash stimulator (NicLED Photic Stimulator) (optional)
Firmware	Resident and Runtime downloadable	Resident and Runtime downloadable
Patient connection and inputs	32 monopolar – 32 plugs 8 bipolar - 16 plugs 1 Thermistor – 2 plugs 2 Reference inputs – 2 plugs 14 ISO GROUND inputs – 14 plugs	36 monopolar inputs – 36 plugs 2 Referemce inputs – 2 plug 2 ISO GROUND inputs - 2 plug

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

EB Neuro, S.P.A.
c/o Ms. Carrie Graham
The Anson Group, LLC
7992 Castleway Group
Indianapolis, Indiana 46250

Re: K041198
Trade/Device Name: Nic36 Amplifier
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWL
Dated: May 5, 2004
Received: May 7, 2004

Dear Ms. Graham:

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). 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) 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

Indications for Use

510(k) Number (if known): K041198

Device Name: Nic36 Amplifier

Indications For Use:

The Nic36 Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR 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)

Miriam C. Provost

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

510(k) Number K041198