FEB 18 2004

K040113

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

807.92(a)(1)

## Submitter Information

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Contact Person: Colleen J. Hittle-Densmore

Date: January 14, 2004

807.92(a)(2)

Trade Name: Sandman SD20 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 Substantial Equivalence Comparison Table.

807.92 (a)(4)

## Device Description

The Sandman SD20 Amplifer is a fully programmable system which provides a total of 22 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 Sandman SD20 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 Sandman SD20 Amplifier contains a Pulse Oximeter module. The data measured from this module is passed to the host computer together with the other channels' data. The MP100 Pulse Oximeter module, developed by Nellcor Puritan Bennett, is substantially equivalent to Nellcor Puritan Bennett's MP400 Pulse Oximeter module cleared with EB Neuro's Mizar Amplifier via K003154.

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

The Sandman SD20 Amplifier system consists of four interconnected units: the headbox, the amplifier box, the PC interface (BE Net/Sandman eLink) and the AC/DC adapter.

807.92(a)(5)

## Intended Use(s)

The Sandman SD20 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 SD 20 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 | 19 (16 monopolar + 3 bipolar) |
| DC channel | 32/40 | 3 (+3 dedicated ) |
| 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) |
| CMMR | >100dB | >100dB |
| Noise | < 1.5 μVpp | <0.5 μVrms(AC) <7 μVrms(DC) |
| Power Supply | External IEC 601-1 mains adapter (standard) Internal batteries (optional) | External IEC 601-1 mains adapter |
| Internal Storage | N/A | N/A |
| Amplifier – PC Interface | PCMCIA or BE Net | BE Net |
| Other Interfaces | 128x64 graph LCD display 5 push buttons | Power on LED (amplifier) LED matrix Ohm Meter (headbox) |
| 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 | 25 x 17 x 6.5 cm | 3.5 x 13.5 x 10.5 cm (amplifier) 12.6 x 9.6 x 2.5 cm (headbox) |
| Weight | 1.5 Kg | 0.3 Kg (amplifier); < 0.3 Kg (headbox) |

| Item | EB Neuro<br>MIZAR Amplifier<br>K003154 | EB Neuro<br>SD 20 Amplifier<br>This Submission |
|---|---|---|
| Isolation | Fiber optic link<br>Patient isolation BF type | Fiber optic link<br>Patient isolation CF type |
| Safety Standards | IEC 601-1-1<br>IEC 601-1-2<br>IEC 601-1-4 | IEC 601-1<br>IEC 601-1-2<br>IEC 601-1-4 |
| System Components | Head box<br>Amplifier<br>AC/DC Adapter<br>PCMCIA or BE Net Interfaces | Head box<br>Amplifier<br>AC/DC Adapter<br>BE Net Interface |
| Firmware | Resident and Runtime downloadable | Resident and Runtime downloadable |
| Head box connection and inputs | 32 monopolar; 8 bipolar; 1 Thermistor | 16 inputs - 16 plugs<br>3 inputs – 6 plugs<br>1 Thermistor dedicated input<br>1 Body position dedicated input<br>1 Pressure sensor dedicated input |
| Pulse Oximetry Module | Nellcor Puritan Bennet MP404 | Nellcor Puritan Bennet MP100 |
| DC Expansion Module Accessory | Yes | Yes |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

EB Neuro, S.p.A.
c/o Ms. Colleen Densmore
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K040113
Trade/Device Name: Sandman SD20 Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological signal amplifier
Regulatory Class: II
Product Code: GWL
Dated: January 14, 2004
Received: January 20, 2004

Dear Ms. Densmore:

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,

for Mark N Melkerson

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): K040113

Device Name: SD20 Amplifier

Indications For Use:

The SD20 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__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

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

510(k) Number K040113