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2 510 (K) Summary K050425

This summary is submitted in accordance with the requirements of 807.92. This summary was prepared on Feb 11, 2005

Submitted By: Grass-Telefactor Product Group
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Proprietary Name : AURA-PSG

Common Name: EEG Amplifier System

Product Category: Electroencephalograph
Regulation number: 882.1400
Medical Speciality: NE
Product Code: GWQ
Product Class: Class II Device

This device claims substantial equivalence to the following:

Grass-Telefactor TS3201/6401:	510(k) number K994142
Grass-Telefactor AS-40 Amplifier:	510(k) number K021807
Grass-Telefactor AURA Amplifier:	510(k) number K033978

Intended Use:
The AURA-PSG amplifier system is intended for recording routine Electroencephalography (EEG) and Polysomnography (PSG). This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in EEG and/or PSG.

2.1 Device Description

AURA-PSG is a compact multi-channel amplifier and data acquisition device designed for electroencephalography (EEG) and polysomnography (PSG) recording applications. It provides for patient safety isolation, signal conditioning, and data sampling.

The AURA-PSG amplifier system consists of two major components: the Amplifier Unit and the Base Station. The Amplifier Unit provides connections for electrodes and sensors and is normally worn by the subject in a vest or pocket. The Amplifier Unit can connect to the Base Station using either a signal cable (tether) or a wireless connection. Both transmit digitized waveform to the Base Station where it is converted to standard network protocols and made available to supporting computers.

AURA-PSG can be used for off-line, ambulatory recording. When used in this fashion, power is supplied by a battery and data is stored in internal memory. When the study is complete, data can be sent to a computer for review.

The Base Station provides Menu selections for configuring the unit, communicating with the host computer, and implementing an electrode impedance test. It contains an LCD that can display status and other information. Power is supplied to the AURA-PSG Base Station through a rear connector that attaches to a medical-grade regulated power supply (+12 volts DC).

The AURA-PSG Amplifier Unit is 5.5 inches x 3.5 inches by 1.0 inches and the AURA-PSG Base Station is approximately 7" x 6" x 2" inches. The Base Station can be attached to a cart arm, mounted on a wall or flat on a tabletop.

2.2 Technological Characteristics

The AURA-PSG and all devices listed as substantially equivalent use the same connections for referential electrodes and employ essentially the same referential amplifier design. All are designed to provide the signal conditioning required for EEG/PSG sensors. When connected to a computer with the appropriate software these systems are designed to monitor EEG/PSG waveforms and store the signals to the computer's hard drive. These products have very similar intended use and safety characteristics.

AURA-PSG and all devices listed as substantially equivalent depend on computer software to provide the majority of waveform filtering and waveform visualization. All are compatible with the Twin software package marketed by Grass-Telefactor. Twin software is compatible with a variety of EEG devices and provides functions for review, filtering and analysis of EEG waveform data. Twin is described in 510K Notification #K012976 (permission to market granted on 2/12/2002).

The essential safety characteristics of these devices are very similar. Each is powered from a low-voltage, medical-grade power supply that acts as safety isolation from mains. Each relies additionally on a second level of safety isolation using transformer coupling and optical techniques to isolate the patient leads from ground.

Both AURA-PSG and AURA are able to record waveforms to internal memory while the device is disconnected from the host computer. In both devices, this memory is removable, non-volatile and approximately the same capacity. Both AURA-PSG and AURA can operate from battery power to record waveforms for several hours without connection to the host computer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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West Warwick, Rhode Island 02893

Re: K050425
Trade/Device Name: AURA-PSG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: October 12, 2005
Received: October 13, 2005

Dear Mr. Sullivan:

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 (240) 276-0115. 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/industry/support/index.html

Sincerely yours,

Barbara Brehm
for

Mark N. Melkerson
Acting 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): K050425

Device Name: **AURA-PSG**

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 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)

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

510(k) Number K050425