AUG 2 9 2002

K 021807

EXHIBIT A

Grass-Telefactor Product Group
Astro-Med, Inc.
West Warwick, RI 02893 USA
Tel: (401) 828-4000
Fax: (401) 822-2430
Contact Person: Peter L Fuller
May 31, 2002

510(k) Summary of Safety and Effectiveness

Grass-Telefactor AS40 Amplifier System

1. Submitter Information

Submitter's Name: Peter L Fuller
Assistant Chief Engineer

Company: Grass-Telefactor Product Group, Astro-Med, Inc.
570 Liberty Street
Braintree, MA 02185

Telephone: (781) 848-2970

Facsimile: (781) 848-2974

2. Identification of the Device

Name of Device: Grass-Telefactor AS40 Amplifier System

Classification: Electroencephalograph, GWQ, Class II, per 882.1400 OLV

3. Equivalent Devices

This product is similar in design, function, and intended use to the Bio-logic SleepScan NETLINK, 510(k) No: K003681 and the Compumedics E-SERIES EEG System, 510(k) No: K000068.

Like these equivalent products, the Grass-Telefactor AS40 is designed to provide the signal conditioning interface (physiological signal amplification, filtering, safety isolation, and digitization) between the patient and a computer platform. When connected by an Ethernet cable or network to a computer with the appropriate software these equivalent systems are designed to monitor physiological signals such as EEG and store the signals to the computer's hard drive. These products have the same intended use and essential performance and safety characteristics.

4. Description of the Device

The AS40 is a compact 40-channel AC amplifier unit designed for electroencephalography and polysomnography recording applications. The AS40 provides for patient safety isolation, signal conditioning (physiological signal amplification and filtering), and digitization. Communications with a single host computer are accomplished using TCP/IP protocol over a 10BaseT Ethernet network or dedicated cable. A host computer, using the appropriate software, sets the sample rate, starts and stops the data transmission, monitors the digital data, and stores it to hard disk.

The AS40 is enclosed in a plastic housing approximately 7" x 6" x 2" (17.78 x 15.24 x 5.08 cm) in size and it can be attached to a cart arm, mounted on a wall next to a patient bed, or sit flat on a tabletop. It can be configured for up to 40 AC and 8 DC channels. An integrated pulse oximeter connection is built into the unit that supports an optional tethered OEM pulse oximeter manufactured by Nonin. The patient connection module or electrode input box is referred to as a personality module in the AS40 system. The personality module connection is located on the top surface of the unit (two 32-pin connectors). The housing for this is a small plastic enclosure that can have up to 40 AC channels with 'SafeLead' (protected) electrode connections, along with a reference and ground 'SafeLead' electrode connection. A customized overlay can be made for customer specific labeling schemes. The personality module can be attached either directly to the AS40 or tethered for easier positioning next to a patient bed. An LCD display with menu controls is located on the top surface of the unit along with the personality module connection. Menu selections can be made for configuring the unit, communicating with the host computer, and implementing the electrode impedance test. The LCD also displays status information such as electrode impedance test values.

Power is supplied to the AS40 through a rear side connector that attaches to a medical-grade regulated power supply (+12 volts DC). A 36-pin connector is also located on the rear side and it allows for the connection of a small plastic tethered auxiliary DC input box (DCM8) with 8 available connections for 3.5 mm jacks. Auxiliary DC inputs can come from devices such as an oximeter, a CPAP unit, or a capnometer. Also available through this 36-pin connector is a patient/event push

button. All other connections (Ethernet, oximeter, photic stimulation control, etc.) are also located on the rear side of the AS40.

5. Indications for Use

The AS40 amplifier system is designed for use in the recording of routine EEG, overnight sleep/EEG (PSG, Polysomnography), and other neurophysiological monitoring applications (EMG and Evoked Potentials). This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in either electroencephalography or polysomnography.

6. Comparison of Technological Characteristics

The design and technological features of the AS40 and the predicate devices are similar. All of the systems provide connections to the patient via a standardized plug-in interface for commonly used EEG electrodes and are intended to record from the same anatomical sites. All of the systems perform amplification and filtering of the bio-potential signals acquired from these electrodes. Each system has an integrated (built-in) oximeter. Each has a means for digitizing the channels and transmitting the sampled EEG and physiological data to a computer over an Ethernet cable or network. Each system has a calibration mode, the means of testing electrode impedances, and means of controlling a flash unit. The performance specifications are also similar for each system, which are well agreed upon by the EEG community (amplifier filter settings, gain, and resolution).

The essential safety characteristics of the devices are identical. Each is powered from a low-voltage DC power supply via a medical-grade power supply as the primary AC safety isolation. Each relies additionally on a second level of safety isolation using either optical, capacitor, or transformer isolation means to isolate the patient leads from ground. Finally, each device is designed to operate with recording and review software separately approved and provided by or recommended by the device manufacturer.

The major difference between these devices is only in the physical packaging, input connection capabilities, and total channel count. The Bio-Logic device is slightly larger with the patient connection box contained in the main unit with an optional tethered version available and it has support for 40 channels. The Compumedics device is smaller than both the Grass-Telecfactor AS40 and the Biologic device but consists of two modules one being the main unit and the other the patient connection box and it has support for up to 57 channels. The Grass-Telefactor AS40 can be a one-piece unit with the patient connection box directly connected to the base unit or separated with the patient connection box tethered and it has support for up to 50 channels.

The following table is provided to demonstrate the AS40's technical characteristics present no significant differences when compared to those of the predicate devices.

Comparison Table

Technical Characteristic	**Grass-Telefactor AS-40**	**Bio-logic SleepScan NetLink**	**Compumedics E-series EEG**
Device Class, Category	II Electroencephalography	Same	Same
Power Supply	Medical-grade power supply	Same	Same
Patient Safety	Patient connections are isolated from ground	Same	Same
Safety and Electrical Standards Met	IEC601-1 UL2601-1 IEC601.2.26 CSA 22.2No.601.1 IEC601-1-2	Not available	IEC601-1 IEC601-2-26 IEC601-1-2
Recording Capacity	48-channel capacity including 8 non-isolated AUX DC channels	40-channel capacity including 8 AUX DC channels	57-channel capacity including 8 non-isolated AUX DC channels
Direct support for an integrated Oximeter	Yes, manufacturer Nonin	Yes, manufacturer Nonin	Yes, manufacturer not specified
Calibration/Use Modes	Yes	Yes	Yes
Built-in (integrated) electrode impedance test	Yes, results displayed on host controlled LCD display on the device	Yes, results displayed using an array of LEDs on the device	Yes, results displayed on host controlled LEDs on the device
Photic (flash unit) Stimulation Control integrated	Yes	Yes	Yes
Host Computer to Device Connection	Industry standard Ethernet interface	Same	Same
Data Output	Digital	Same	Same
Anatomical Sites	Same	Same	Same

Comparison Table (Continued)

Technical Characteristic	Grass-Telefactor AS-40	Bio-logic SleepScan NetLink	Compumedics E-series EEG
A/D Resolution	16-bit, simultaneous sampling	22-bit, simultaneous sampling	8, 12, or 16-bit simultaneous sampling
Sampling Rate	Up to 800 Hz	128 – 2048 Hz	Up to 512 Hz
Noise	< 2μVpp	< 2μVpp	0.5μVrms
CMRR	>80dB	> 100dB	>115dB differential mode, >105dB single ended
Input Impedance	10 MOhms	Not available	> 100MOhms
Low-Frequency Cutoff	0.16 Hz	0.1 Hz	0.16 Hz
High-Frequency Cutoff	100 Hz	Not available	107 Hz

7. Testing

The Grass-Telefactor AS40 system is in the process of being extensively tested to the applicable safety, EMI and EMC standards for medical electrical devices, and specifically EEG equipment. Third party testing and certification to IEC601-1, IEC601-1-2, IEC601-2-26, UL2601-1, CSA22.2No.601-1 is also in process and will be completed before we commence shipment of this device.

Additional performance testing and bench testing has been completed to verify operation of all functional equipment and performance specifications.

In conclusion, the Grass-Telefactor AS40 amplifier system is as safe and effective as the predicate devices currently marketed by Bio-Logic Corporation and Compumedics and raises no new safety or effectiveness concerns.

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

Grass-Telefactor Product Group, Astro-Med, Inc.
Peter L. Fuller
Assistant Chief Engineer
570 Liberty Street
Braintree, Massachusetts 02185

APR - 9 2012

Re: K021807
Trade/Device Name: Grass-Telefactor AS40 Amplifier System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): May 31, 2002
Received (Date on orig SE ltr): June 3, 2002

Dear Mr. Fuller:

This letter corrects our substantially equivalent letter of August 29, 2002.

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,

Kesia 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

http://www.fda.gov/cdrh/ode/indicate.html

510(k) Number (if known): K021807

Device Name: Grass-Telefactor AS40 Amplifier System

Indications for Use:

The AS40 amplifier system is designed for use in the recording of routine EEG, overnight sleep/EEG (PSG, Polysomnography), and other neurophysiological monitoring applications (EMG and Evoked Potentials). This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in either electroencephalography or polysomnography.

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

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

(Posted July 1, 1998)

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

510(k) Number K021807