K994142

MAR - 6 2000

EXHIBIT A

Grass® Instrument Division
Astro-Med, Inc.
West Warwick, RI 02893 USA
Tel: (401) 828-4000
Fax: (401) 822-2430
Contact Person: Steve Johnson
December 1, 1999

510(k) Summary of Safety and Effectiveness

Grass® TS3201/6401 EEG Amplifier

1. Submitter Information

Submitter's Name: Stephen E. Johnson
V.P. or Research & Development

Company: Grass Instrument Division, 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® TS3201/6401 EEG Amplifier System

OLV

Classification: Electroencephalograph, GWQ, Class II, per 882.1400

3. Equivalent Devices

This product is similar in design, function, and intended use to the Bio-Logic CEEGRAPH 128-channel Recording System (K973883) and the Telefactor H2O "Tethered-option" EEG recorder system (K992291).

Like these equivalent products, the Grass® TS3201/6401 is designed to provide the signal conditioning interface (EEG signal amplification, filtering, and safety isolation) between the patient and a personal computer platform. When paired with a computer and EEG software, these equivalent systems are designed to monitor the EEG signals in a real-time graphical "chart" view on the computer monitor, store the signals to the computer's hard drive, replay the data on-screen, simplify the marking and tabulation of diagnostically significant events and measurements, and generate summary reports and graphs for technologist/physician review. These products share the same intended use and essential performance and safety characteristics.

4. Description of the Device

The Grass TS3201/TS6401 systems are 32-channel and 64-channel (respectively) devices for acquiring and conditioning EEG signals and transmitting them to a personal computer for display and storage. The system consists of one or more miniature pager-size 32-channel preamplifier units, which plug into a small "belt-pack" designed to be worn by the patient. The belt-pack provides further signal conditioning, safety isolation and communication to a remotely located interface panel and data acquisition computer.

Up to two TS3201 or TS6401 belt-packs, in any combination, can be plugged into the interface panel to provide for up to 128 channels of EEG monitoring from a single subject. Each belt-pack includes one additional pair of inputs for standard electrodes for monitoring EOG (eye movement) or ECG. Additionally, each belt-pack also includes a patient call pushbutton, which can be used to signal the control room or automatically trigger event marks or recording devices.

5. Indications for Use

The TS3201/6401 amplifier system is designed for use in the recording of routine EEG, long-term EEG with patient video and overnight sleep/EEG recording applications (Polysomnography). This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in electroencephalography.

6. Comparison of Technological Characteristics

The design and technological features of the TS3201/6401 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 pre-amplification and filtering of the bio-potential signals acquired from these electrodes. Each has a means for sampling the channels at a predetermined or configurable rate and transmitting the sampled EEG data to a personal computer. Each system has similar performance specifications, 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 be operated 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, expansion capabilities, and communication interface. The Bio-Logic device is all contained within one large box that can be internally expanded with additional amplifier modules from 32 channels to 128 channels. The Telefactor unit is limited to only 32 channels, but is substantially smaller than the Bio-logic device and can be worn by the patient. The Grass TS3201/6401 sub divides the systems into separate functional modules that can be externally combined to provide both light-weight, wearable amplifiers with the ability to expand from 32 to 128 channels in 32 channel increments.

7. Testing

The Grass TS3201/6401 system has been 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, UL2601-1, CSA22.2#601-1 has been completed or is in process.

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

In conclusion, the Grass TS3201/6401 system is as safe and effective as the predicate devices currently marketed by Bio-Logic Corporation and Telefactor Corporation 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

Mr. Stephen E. Johnson
Vice President, Research and Development
Grass Instrument Division
Astro-Med, Inc.
570 Liberty Street
Braintree, Massachusetts 02185

APR - 3 2012

Re: K994142
Trade/Device Name: Grass TS3201/6401 EEG Amplifier System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): December 1, 1999
Received (Date on orig SE ltr): December 8, 1999

Dear Mr. Johnson:

This letter corrects our substantially equivalent letter of March 6, 2000.

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

510(k) NUMBER (IF KNOWN): K994142

DEVICE NAME: TS3201/6401

INDICATIONS FOR USE:

The TS3201/6401 amplifier system is designed for use in the recording of routine EEG, long-term EEG with patient video and overnight sleep/EEG recording applications (Polysomnography). This device is intended to be used only by physicians, technicians, or other medical professionals that are trained in electroencephalography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994142