K012976

2-12-02

EXHIBIT A

Grass-Telefactor Division

Astromed-Med, Inc.

West-Warwick, RI 02893 USA

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Contact Person: Jim Bryan

August 15, 2001

1. Identification of the Device

Classification Name: Electroencephalograph, 84GWQ, Reg. #882.1400 OLV

Common/Usual Name: EEG Review Software

Proprietary-Trade Name: Grass-Telefactor TWin PLUS Software

2. Equivalent Legally Marketed Devices

This software is functionally equivalent in design and function to that of the GRASS GAMMA software package and the Telefactor BEEHIVE, and the Telefactor SZAC Seizure Analysis Computer.

3. Indications for Use

This software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG and PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. Its specifications and features are especially well suited to electroencephlography, polysomnographic sleep recordings, and long term recordings used in epilepsy diagnosis.

4. Theory of Operation and Description of the Device

TWin PLUS will become the universal review package for all GRASS-Telefactor EEG systems. Further the TWin PLUS software package is intended for use with a number of hardware EEG input devices. It utilizes the windows operating system to manage four or more simultaneous ongoing tasks which include:

- Real-time collection and formatting of real time EEG and other physiological parameters

- Real-time display of the foregoing parameters in waveform or numeric format as the data and user may require.
- Real time analysis of EEG waveform data to identify events which may be epileptoform in nature and hence require special attention from professionals in attendance – SZAC analysis.
- Data collection and recording to disk of real time video and audio data, usually an image of the patient being monitored.
- Review and analysis of previously recorded data including the ability to look-back to old data while real-time recording of ongoing data is in progress.

EEG Input Amplifiers:

The TWin PLUS software package is intended to work with a number of different amplifier systems with various digital interface modes. Each of these hardware devices have or will have their own separate 510(k) marketing authority.

These amplifiers choices include:

- Current BEEHIVE amplifiers which use a special purpose digital interface card for already digitized data.
- The same BEEHIVE amplifiers using a USB interface for the data.
- GRASS-Telefactor TS amplifiers using a computer resident card for A to D conversion of their multiplexed analog data stream.

Data Formatting and Storage:

All data is stored in a format (TUFF) as near the original input as possible at sample rates appropriate for the data type. Primary storage is either local or remote hard disk (network server). Provisions exist for archiving to several appropriate digital archive media, most frequently CD ROM.

Montaging Capability:

The TWIN PLUS software has provision for labeling data channels with electrode names and then displaying waveforms as the algebraic difference of any electrode pair. The playback montage also specifies default digital filter settings.

Analysis:

Specific sections of data can be selected easily for further analysis including frequency and amplitude measurement, potential mapping, spectral analysis, and frequency band mapping.

Flagging of Epileptoform EEG Data Sequences (SZAC):

The SZAC program module uses the identical software algorithm developed and proven in the SZAC Computer previously marketed by Telefactor (K870450) This system is in wide use in the medical community, particularly in epilepsy centers around the world. Grass-Telefactor makes no claims for diagnostic accuracy of this algorithm, it is merely a device which marks particular EEG passages for diagnostic consideration either as seizures or as spikes.

EEG Data BASE:

An EEG data base feature associates stored EEG data with patient name, date and appropriate clinical parameters entered by the operator, and provides convenient means for accessing that data for review.

Digital Video Recording:

TWIN software uses the output of an appropriate video capture card in the host computer to digitize, compress and store patient image data. Provision is included to play back video data synchronized with the EEG waveform display.

Semi Automatic Sleep Scoring:

TWin PLUS includes the next iteration of the Semi Automatic Sleep Scoring System (SASSY K860219). This system functions to display polysomnographic data in standard page sizes and provides means a review operator to assign a sleep stage notation to each page.

Report generation and printout are provided for each study with reported parameters which can be tailored by the particular laboratory using the device.

A software option is provided for automatic analysis of SaO2 and respiration data to mark apnea and desaturation events for professional review and classification. A similar module analyzes EMG waveforms to mark periodic leg movements. In each case no diagnostic classification is made without a decision based on the review of a qualified professional.

These routines are supplied without any claims for accuracy and the professional can use or ignore them at his own discretion. In each case decision thresholds are adjustable and can be set by the person reviewing the data.

5 Comparison Matrix

Technical Characteristic	GRASS-Telefactor TWin PLUS	GRASS GAMMA	Telefactor SZAC 16 Seizure Analysis Computer	Telefactor BEEHIVE 64
Device Class	CLASS II	CLASS II	CLASS II	CLASS II
Intended User	Medical Professional	Medical Professional	Medical Professional	Medical Professional
Operating System	Windows 98 or 2000	Windows 98 0r 2000	DOS	DOS
Max Channels	136	36	16	64 (128 for other models)
Sample Rate	1000 Hz Max	1000 Hz Max	200	200
Amplifier control	RS232	RS232	Manual	RS232
Recorder Update Mode	Wiper Bar	Wiper Bar	Scrolled Display	Scrolled Display
Monitor Resolution	1600 x 1200	1600 x 1200	1024 x 440	1024 x440
Data Storage	Local or Remote hard disk	Local or remote hard disk	Local or remote hard disk	Digital VCR
Primary Data Access	Random	Random	Random	VCR sequential
User Input	Mouse/keyboard	Mouse/keyboard	Keyboard	Keyboard
Synchronized Patient Video	Yes			Yes
Seizure Event Marking	Yes		Yes	
Spike Event Marking	Yes		Yes	
Apnea Event Marking	Yes	Yes		
Desaturation Event Marking	Yes	Yes		
PLM Marking	Yes	Yes		
Staging/scoring method	Manual/computer assisted	Manual/computer assisted		
Sleep Report Parameters	Yes	Yes		
Epilepsy Parameters	Yes		Yes	Beehive 7

6 Discussion:

The TWin PLUS software is primarily a composite of the three referenced substantially equivalent devices with enhanced capacity permitted by the state-of-the-art in electronic data handling. Faster computers, less expensive disk capacity and multi-tasking operating systems have permitted combining all the features of the referenced products into a single useful modular software package.

None of the products features have any impact on the safety of the patient or operator. Although both TWin PLUS and GRASS GAMMA (NIGHT VISION) have the capability to control the data acquisition

amplifier settings, neither are required for the safe operation of the amplifiers that they are designed to control, nor are they capable of impacting on the safety of the amplifier systems.

All of the products are designed to be operated by trained medical professionals and the data collected is reviewed in its entirety by trained medical professionals. None of the products claims to be in and of itself "diagnostic".

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. John B. Chatten
President
Grass-Telefactor Division
Astro-Med, Inc.
West-Warwick, Rhode Island 02893

APR - 9 2012

Re: K012976
Trade/Device Name: Grass-Telefactor Twin PLUS Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): December 7, 2001
Received (Date on orig SE ltr): December 11, 2001

Dear Mr. Chatten:

This letter corrects our substantially equivalent letter of February 12, 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,

for Keoia Alexander

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): K012976

Device Name: TWIN Plus

Indications for Use:

This software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG and PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. It is suitable for digital acquisition, display, comparison, analysis, and archiving of EEG potentials and other rapidly changing physiological parameters.

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

Concurrence of CDRH, Office of Device Evaluation (OIDE)

Miriam C. Provost

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

510(k) Number K012976

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)