K970951

EXHIBIT A

MAY 19 1997

Grass® Instrument Division
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February 20, 1997

510(k) Summary of Safety and Effectiveness
Grass® NightVision Software

1. Identification of the Device

Classification Name: Electroencephalograph, OLV, Reg.# 882.1400

Common/Usual Name: Polysomnograph/Electroencephalograph Software

Proprietary-Trade Name: Grass® Brainware PSG/EEG Software

2. Equivalent Legally Marketed Devices

This product is similar in design, function, and intended use to the Stellate Systems Eclipse software and the Melville Diagnostics Sandman™ software systems.

Like these equivalent software products, Grass® NightVision is designed to run on a personal computer platform and interface with signal conditioners/amplifiers to: monitor the signals in a real-time graphical "chart" view on the computer monitor, digitize and 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.

4. Theory of Operation and Description of the Device

The Grass® NightVision is a Microsoft Windows95™ application software package for monitoring, recording, and reviewing physiological signals. It includes features for assisting the user with making measurements, marking significant events, and tabulating the events for easier interpretation. The software consists of two major modules, the Recorder and the Reviewer, and several minor modules for setup, montage editing, file management, and report generation. Together with a personal computer and a set of physiological signal conditioners (like the Grass® Model 15 amplifier system), the NightVision software enables the user to replace or upgrade traditional strip-chart recorders used in the sleep laboratory with modern, digital recording and review methods.

The Recorder module interfaces with an off-the-shelf A/D board (National Instruments AT-MIO-64E3) using a software driver library supplied with the board. A set of user specified channels (1 to 32) are sequentially sampled, digitized, and displayed on the screen in graphical, chart-recorder format, mimicking the traditional paper based strip-chart recorders. The Recorder module allows the user to specify the digitizing sample rate and a recording montage (the channel set, labels, and amplifier settings) to use for the recording session. The operator has manual control over the start and stop of the recording, much like a tape recorder. In addition, the user can vary the settings of each on-screen "pen" (color, position, sensitivity, etc.) and can also make user definable event marks for annotation of the recording. The effect is a "virtual" strip-chart recorder where the signal data is saved to the computer's hard disk. This module creates two files, the waveform data file and a log file of the user keyed real-time annotations.

The Reviewer module allows the technologist/physician to review a previously recorded data file on-screen. The recording data is displayed in a high-resolution window with controls for paging forward and backward, expanding/compressing the time scale, adjusting the trace settings (color, position, sensitivity, etc.), and for making accurate measurements of amplitude, time, and other statistics. Additionally, tools are provided for tagging each "page" of data with a "sleep stage" and for adding event mark tags to significant waveform segments. This module creates one new file, the "scoring" file, which contains a table of all of the "pages" in the file with the tabulations of the sleep stages, user entered event marks, and any other information derived during the reviewing session.

The Report Generator module takes the "scoring file" table generated during the review process and processes it into a more easily readable, condensed and formatted report. From the raw scoring tabulations, the report generator creates totals, averages, minimums, maximums, and correlates the different events. The result is a text report that reduces an average of about 1000 pages of recorded raw data into 2 to 5 pages of summary data and graphs for easier interpretation.

The Montage Editor and File Management utilities are for creating and editing recording setups (channel labels, amplifier settings, trace attributes, etc.) and for copying/archiving recording files, respectively.

Important Note:

The Grass® NightVision software relies completely on manual user assignments of sleep stage and other significant event marks. NightVision uses the power of the computer whenever possible to aid and speed the scoring and review of the data files by keeping track of relevant signal information (duration, time, signal size, etc.) associated with each user marked event.

Unlike some competitive products on the market, it makes no determination of clinically significant events automatically using algorithms (like apneas or sleep stages). The software does not make any judgement of normality or abnormality of any displayed or recorded signal data or the results or any analysis. The software is not represented as being in and of itself diagnostic.

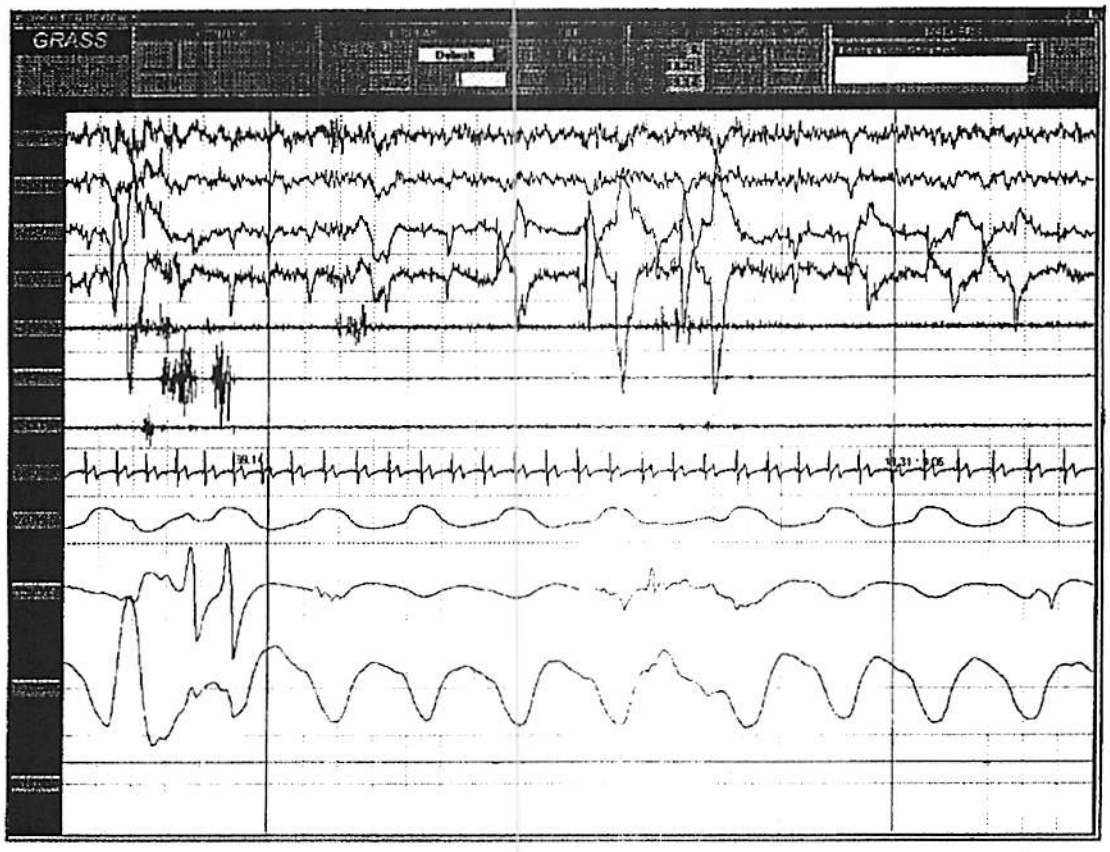
Grass® Instruments supports the position of the American Sleep Disorders Association that every page of the recording must be manually reviewed due the complexity of the multi-parameter recordings and the confounding aspects of movement and other artifacts typical in an all-night sleep recording.

5. Draft Advertisement

®*Grass* NightVision PSG

Digital PSG/EEG Software

Astro-Med, Inc.



Grass NightVision is state-of-the-art Windows95™ polysomnography software with the features, versatility, and quality that you've come to expect from *Grass*. Together with the new Model 15 Amplifier Neurodata Amplifier System and specially developed electrode selectors and accessory hardware, NightVision completes the first digital PSG ready to carry on the Grass tradition as the Gold Standard in sleep recordings.

Major Features:

- Embedded control of the Model 15 Neurodata Amplifier system
- Support for 32 channels of acquisition and display
- Support for simultaneous acquisition of two beds
- Simple and accurate calibration of input signal into user units
- Real-time "look-back" and pre-scoring of recorded data, with no memory limits
- Real-time digital filtering, display gain, and trace position control
- Interactive control of all channel parameters "on-the-fly"
- Real-time event marking - 24 user definable event marks plus "on-the-fly" text
- Special analysis functions for the scoring/analysis of sleep parameters
- Built in Windows95™ networking with optional reading stations and printers

NightVision PSG Software

Designed by *Grass* specifically for polysomnography, NightVision is a brand new Windows95™ software application for recording all-night PSG studies, assisting in rapid review and scoring, and for generating flexible PSG reports. Taking full advantage of the Model 15 amplifier system, NightVision manages the creation and use of multiple recording montages, including downloading the amplifier settings automatically to the Model 15. Data is presented in familiar chart-recorder format in super high-resolution displays with amazing flexibility and fully interactive on-screen controls. Multitasking allows the simultaneous review of previously recorded files or even an on-going recording, with the ability to start scoring on-line. NightVision combines the power and configurability of research grade software with the simplicity and ease-of-use required in a clinical setting.

In accordance with American Sleep Disorders Association guidelines for polysomnography, NightVision uses no automated algorithms for staging sleep or scoring respiratory events. Instead, fast and convenient on-screen scoring tools combined with lightning fast tabulation of scoring results and report generation result in faster scoring - without sacrificing the quality and thoroughness that hands-on, expert scoring guarantees.

Specifications	
Montages	Unlimited number of user definable recording montages
Channels	1 to 32 channels per recording montage
Display Settings	Up to 16 user definable display settings formats per recording montage
Display parameters	Trace on/off, Trace color, Trace line style, grid width, baseline, sensitivity, digital filters (low, high), digital display on/off
Vertical resolution	12-bits (12 nanovolts - 2.44 mV per bit depending on amplifier gain)
Recorder sample rate	0.1 - 1000Hz, all channels
Real-time Annotation	23 predefinable markers plus one comment key
Scoring method	Computer assisted (non-automated) with on-screen scoring tools
Scoring output	Editable scoring text file for complete disclosure, allows user overrides
Report generation	Sleep summary; arousal summary; latencies; respiratory disturbance summaries, details and indices; O2sat analysis; correlations of previous with REM/NREM and body position; graphical displays of selected channels, trends, events, and hypnograms.
Archive Media	Recordable CD-ROM (CD-R)
Cursor Measurements	2 on-screen cursors: amplitude, time, duration, min, max, std.dev., integral, area, rate, peak-peak
Analysis Functions & scoring aids	trend, zoom, FFT, hypnogram, goto mark, goto epoch, goto time, marker info,
Time axis settings	1 second/page to 2 minutes/page
Print functions	print epoch or epoch range, variable timebase compression. Special analysis views also include print window options.
Save functions	save epoch range in NightVision or common ASCII formats. Save functions also available in special analysis windows.

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
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APR - 9 2012

Re: K970951
Trade/Device Name: Grass® Brainwave Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV
Dated (Date on orig SE ltr): February 20, 1997
Received (Date on orig SE ltr): March 14, 1997

Dear Mr. Johnson:

This letter corrects our substantially equivalent letter of May 19, 1997.

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,

Tresia 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): K970951

Device Name: Grass Brainwave Software

Indications For Use:

Grass Brainwave Software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG/PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. Its specifications and features make it especially well suited to electroencephalography and polygraphic sleep recordings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K970951

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)