K 123915

APR 2 4 2013

510(k) SUMMARY (as required by 21 CFR 807.92)

Device Name: DE-48-Plus Disposable Electrodes

COMPANY:
Grass Technologies
Division of Astro-Med, Inc.
53 Airport Park Drive
Rockland, MA 02370
Establishment Registration Number: 1218414

CONTACT:
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TRADE NAME: DE-48-Plus Disposable Electrodes

COMMON NAME: Non-invasive Disc Electrodes

CLASSIFICATION NAME: Electrode, Cutaneous

REGULATION NUMBER: 882.1320

PRODUCT CODE: GXY

SUBSTANTIAL EQUIVALENCE

Grass Technologies believes that the DE-48-Plus Disposable Electrodes are substantially equivalent to the Rhythmlink Disc Electrodes as marketed under K061148 by Rhythmlink International, FDA Reg# 1067162 and to Grass Technologies' Gold Electrodes as marketed *by Grass Technologies* in the US prior to 1976.

DEVICE DESCRIPTION

The Grass Technologies DE48-Plus Disposable Electrodes (various lengths) are non-invasive, cutaneous devices, applied directly to the skin, and used in the acquisition of physiological signals for the purpose of montoring and recording Electroencephalograph (EEG), PSG and similar physiological parameters.

Non-invasive, disposable surface electrode discs (Cutaneous Electrodes), as included in this submission, are applied to the skin using a cream or gel for adhesion. Their purpose is to pick up and transfer microvoltage signals, as generated by the body, to recording equipment, for the purpose of monitoring and recording associated with electroencephalography and electromyography. The new Grass DE-48-Plus electrodes, as with the BNT predicate, are manufactured with a circular, raised cup body molded from ABS plastic and coated with silver/silver chloride (Ag/AgCl). The disc is adhered to a lead wire which is covered with heat shrink tubing and terminates with a molded

connector that conforms to DIN 42-802 for electrical safety. Grass DE-48-Plus Electrodes connect to, and work with, any EEG equipment, without special attachments.

The DE-48-Plus electrodes are made up of the following materials (same or equivalent to the Rhythmlink predicate).

Cup Disk: ABS Plastic with an Ag/AgCl coating which is nominally measured at 10mm (8.5 to 10mm).

The connecting wire which is manufactured from 28AWG stranded Tin Copper conductor with soft PVC insulation.

Wire crimped to Cup Electrode using Tin plated copper tubing.

Terminal connected with Alex crimp type, 24-30AWG Brass, Tin plated, Molded in Palprene.

INDICATIONS FOR USE

The Grass "DE-48-Plus Disposable Electrodes" are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials.

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s)

The Grass and Predicate Surface Disk Electrodes are non-invasive, cutaneous devices used for the acquisition of signals from the body for the purpose of monitoring and recording EEG, EMG and Evoked Potentials (EP). The Grass DE-48-Plus Disk electrodes are manufactured from ABS Plastic with an AG/AgCl coating; with lead wire manufactured from 28AWG stranded tin copper conductor with soft PVC insulation; electrode to wire crimp with tin plated copper tubing; and an Alex crimp type terminal (24-30 AWG Brass, tin plated, molded in Palprene) which conforms to DIN 42-802 for electrical safety and is the same/equivalent design as the predicate Disc Electrodes. Skin contact materials do not include the use of any color additives.

PERFORMANCE DATA

Product performance characteristics [Resistance, Model Surface, Impedance and Frequency Response] of the Grass DE-48-Plus electrode was found, through appropriate testing to be substantially equivalent to the predicate Grass Gold and the Rhythlink BNT Disk Electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2013

Grass Technologies, Inc.
Mr. Phillip Soares
53 Airport Park Drive
Rockland, MA 02370

Re: K123915
Trade/Device Name: DE48-Plus Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 27, 2013
Received: February 21, 2013

Dear Mr. Soares:

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 contact 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. 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123915

Device Name: DE48-Plus Disposable Electrodes

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123915