5. 510(k) Summary

K071118

EEG Surface Electrode System

SEP - 7 2007

Company Name:	Ives EEG Solutions, Inc.
Contact:	Mr. John Ives
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Email:	jives@uwo.ca
Summary Date:	April 12, 2007
Trade Name:	EEG Surface Electrode System
Model Number:	GCE, SCE, SCE^S and CPE^S
Common Name:	Surface Electrode, Cutaneous electrode
Classification Name:	21 CFR 882.1350, Cutaneous Electrode GXY

Main Predicate Device:	510(k) Number:	marketed before 1974 (see note below)
	Manufacture:	Grass Instruments, Inc, Quincy, MA
	Trade Name:	Surface EEG Electrode
	Product Code:	GXY
Other Predicate Devices:	510(k) Number:	K032278
	Manufacture:	AMBU, Inc.
	Trade Name:	EEG/EP Cup Electrode
	Product Code:	GXY
	510(k) Number:	K022197
	Manufacture:	The Electrode Store
	Trade Name:	Cutaneous Electrode
	Product Code:	GXY

Description of Electrodes

The cutaneous surface electrode (GCE, SCE, SCE^S and CPE^S) are electrodes that are all applied to the surface of the patient's skin, they are non-invasive. These electrodes are used for the recording of electroencephalography (EEG), evoked potential (EP) as well as the ground and reference associated with the recording. They consist of a disc or cup made from a variety of materials, which include, gold, silver, conductive plastic, Ag-Ag/Cl, that have long been used for this intended purpose throughout the industry. The recording disc is permanently connected to a lead wire. This joint is then covered in a heat-shrink tube so as not to allow exposed lead wires and also to provide a strain relief. The lead wires are insulated with a Teflon insulation or equivalent. The lead wires are

short and terminate in a small mass connector than conforms to DIN 42-802 for electrical safety. This small mass connector mates with a harness system as per K062880 (an Ives EEG Solutions 510K describing a Subdermal Wire Electrode System) which connects to the EEG recording instrument using molded "touch-proof" connectors which also conform to DIN 42-802.

Intended Use of Electrodes

The cutaneous, surface electrode system is intended for use for the recording and monitoring of the electroencephalography (EEG), evoked potential (EP) and the ground and reference associated with these recordings.

NOTE: Mr. Albert Grass began marketing EEG electrodes for general use when he established his company (Grass Instruments, Inc, Quincy, MA) in 1935. These cutaneous, surface cup electrodes have been continuously marketed under the Grass name by Astro-Med, Inc., West Warwick, RI. Advertising for these electrodes can be seen in copies of the Journal of Clinical Neurophysiology from 1949 to 1974 as well as in the early publications of the American Journal of Electroneurodiagnostic Technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ives EEG Solutions, Inc
% Mr. John Ives
President
6325 Rideau Valley Drive
Manotick, Ontario
Canada, K4M 1B3

SEP - 7 2007

Re: K071118
Trade/Device Name: EEG Surface Electrode System
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 28, 2007
Received: September 4, 2007

Dear Mr. Ives:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D Rumm MD MPH
DEP D.F
9/7/07

Mark N. Melkerson
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number:
Device Name: EEG Surface Electrode System
Indications for Use: The cutaneous, surface cup electrode system is intended for use in the general recording and monitoring of the electroencephalography (EEG), evoked potential (EP) as well as ground and reference related to the EEG and EP recording.

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

md

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

510(k) Number k071118