# 510(K) SUMMARY

Date: February 25, 2002

OCT 0 8 2002

Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Contact: Dawn E. Frazer
Vice President
Regulatory Affairs & Quality Assurance
(978) 670-2422 x243
dfrazer@physiometrix.com

Subject Device: Model 4310 PSArray$^2$ EEG Electrode

Classification: Class II, CFR 21 Part 882.1320, Cutaneous Electrodes

Intended Use: The Physiometrix PSArray$^2$ EEG Electrode is applied directly to the patient's skin to enable recording of electrophysiologic signals (such as EEG).

Description: The Physiometrix Model 4310, PSArray$^2$ EEG Electrode, is a single-use, disposable, pre-gelled electrode array. The PSArray$^2$ is comprised of six (6) electrodes located at F7, Fp1, FpZ', FpZ, Fp2 and F8. The electrode is packaged with 1 electrode per pouch, 25 pouches per box and 4 boxes per case.

The electrodes are mounted in a polyethylene foam coated with a pressure sensitive adhesive. The electrode pad is an area of silver/silver chloride ink that is connected to cable connector by a silver ink trace. An electrolyte gel is held in place over the electrode pad by a open-cell polyurethane sponge located in wells created by the foam basepad. The electrolyte gel was selected for its low impedance properties. No pre-application prepping is required to achieve adequate impedance levels for operation of the PSA4000.

The PSArray$^2$ EEG Electrode is connected to the PSA4000 System via a patient cable that attaches to the substrate connector. The PSArray$^2$ is designed for use with the PSA4000 System.

Predicate Device: K001055, Model 4300, PSArray EEG Electrode

Similarities: The PSArray$^2$ is similar to the predicate device in the following ways:
a. The intended use is same.
b. The technology is same.
c. The materials are the same.

Differences: The PSArra$^2$y is different from the predicate device in the following way:
a. The PSArray$^2$ has 6 electrodes while the predicate device has 7 electrodes.

Test Results: Electrical testing was conducted in accordance with the American National Standard for Disposable ECG Electrodes, AAMI/ANSI EC-12 (1991). The PSArray$^2$ device exceeded requirements indicated in the standard.

Biocompatibility testing was conducted in accordance with the International Standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing and FDA Guidance, "Protocol for Dermal Toxicity Testing for Medical Devices In Contact with Skin." The skin contact materials were determined to be safe for contact with skin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Physiometrix, Inc.
Dawn E. Frazer
Vice President, Regulatory Affairs & Quality Assurance
Five Billerica Park
101 Billerica Avenue
North Billerica, Massachusetts 01862

Re: K020670
Trade/Device Name: PSArray² EEG Electrode Model 4310
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: October 7, 2002
Received: October 7, 2002

Dear Ms. Frazer:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

| | |
|---|---|
| Applicant: | Physiometrix, Inc. |
| 510(k) Number (if known) | Not assigned |
| Device Name | Model 4310 PSArray$^2$ EEG Electrode |
| Indications For Use | The Physiometrix PSArray$^2$ EEG Electrode is applied directly to the patient's skin to enable recording of electrophysiologic (such as EEG) signals. |

(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)

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

510(k) Number K020670