

MAY 10 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

Date: April 22, 1996

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

Contact: Dawn E. Frazer
Director, Regulatory Affairs & Quality Assurance
(508) 670-2422
(800) 474-9746

Subject Device: Model 1220 , OR e-Net (54 - 62 cm)

Predicate Device: K930080, HydroDot NeuroMonitoring System

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

Description: The OR e-Net is designed to fit patients with a head size in the range of 54 - 62 cm in circumference. It is constructed using the same materials and manufacturing processes as the predicate device, Large e-Net which is described in K930080.

Intended Use: The e-Net serves two functions as a part of the Hydro Dot NeuroMonitoring System. First, it locates the EEG electrodes according the 10-20 International System. Secondly, it conducts the electrical signal sensed by the electrodes from the skin to the EEG equipment.

Indication for Use: EEG recording in OR environment.

Design/Materials: The OR e-Net is fabricated from the same materials as the larger version. Two changes were made to make the product more suitable for the OR environment. First, the material located below the ear was removed and secondly, the inion tab was extended to allow it be secured to the neck.



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

Ms. Dawn E. Frazer
Director, Regulatory Affairs & Quality Assurance
Physiometrix, Inc.
Five.Billerica Park
101 Billerica Avenue
N. Billerica, Massachusetts 01862

APR - 9 2012

Re: K961609
Trade/Device Name: Model 1220, OR e-Net (54-62 cm)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated (Date on orig SE ltr): April 22, 1996
Received (Date on orig SE ltr): April 25, 1996

Dear Ms. Frazer:

This letter corrects our substantially equivalent letter of May 10, 1996.

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" (21 CFR 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,



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

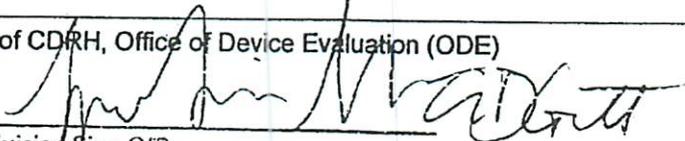
Enclosure

Physiometrix, Inc.
510(k), Premarket Notification
OR e-Net (54 - 62 cm)

510(K) Number (if known): Unknown K961609
Device Name: Model 1220, OR e-Net (54 - 62 cm)
Indications for Use: Headpiece for EEG Monitoring in Operating Room

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K961609

Prescription Use
Per 21 CFR 801.109)

OR

Over-The-Counter Use

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