K103103

DEC - 8 2011

II. 510(k) Summary of Safety and Effectiveness

PressOn™ electrode

General Information

Criteria	*Information*
Trade Name	PressOn™ electrode
Catalog/Model Number	PR01
Common Name	Needle (electroencephalograph) electrode
Classification	21 CFR 882.1350 – Needle electrode Class II; product code: GXZ
510(k) Submitter	Persyst Development Corporation 3177 Clearwater Drive Prescott, AZ 86305
Contact Person	Scott B. Wilson Chief Executive Officer Persyst Development Corporation scottw@persyst.com 858.755.4568 (phone) 858.755.4565 (fax)

Summary of Substantial Equivalence

The PressOn electrode does not raise any new safety or effectiveness issues and is substantially equivalent to legally marketed needle electrodes that are in commercial distribution, and have been determined to be substantially equivalent to devices in commercial distribution, prior to May 28, 1976.

Date: October 5, 2010

Substantially Equivalent Devices

Manufacturer	*Substantially equivalent device*	*510(k)*
Rhythmlink International, LLC Cayce, South Carolina USA	Rhythmlink subdermal needle electrodes	K022914

Device Description

The PressOn electrode is a single-use, disposable EEG electrode. The electrode is very small, with a footprint of approximately 0.6 cm and a very thin (~0.004 inch) height profile. It is made from a super-elastic Nitinol and is flexible. The electrode has 3 legs (a tri-pod configuration) that each terminate in micro-teeth that penetrate the top layers of the scalp dermis during subdermal electrode placement.

The PressOn electrode is used in conjunction with an accessory PressOn lead that is provided non-sterile and is reusable. The lead is approximately 48" in length and is used to connect one of the PressOn electrodes to a commercially available EEG monitor. The EEG monitor/ equipment is not part of the PressOn device offering.

Indications for Use

The PressOn™ electrode is intended for use in the recording of the electroencephalogram (EEG), the evoked potential (EP), or as ground and reference in an EEG or EP recording.

Testing

The PressOn electrode underwent biocompatibility, bench and performance testing and demonstrated acceptable results in all testing.

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

Persyst Development Corporation
c/o Mr. Scott B. Wilson
Chief Executive Officer
3177 Clearwater Drive
Prescott, Arizona 86305

DEC - 8 2011

Re: K103103
Trade/Device Name: PressOn Electrode
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: November 18, 2011
Received: November 21, 2011

Dear Mr. Wilson:

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,

Kevia 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

I. Indications for Use Statement

510(k) Number (if known): _____

Device Name: ***PressOn™ electrode***

Indications for Use:

The PressOn™ electrode is intended for use in the recording of the electroencephalogram (EEG), the evoked potential (EP), or as ground and reference in an EEG or EP recording.

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

Concurrence of CDRH, Office of Device Evaluation ~~(ODE)~~

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103103