K123776

DEC 19 2012

PMT Corporation
510(k) Summary

Submitter's Name, Address, and Date of Submission

Al Iversen
President
PMT Corporation
1500 Park Road
Chanhassen, MN
Phone: 952-470-0866
Fax: 952-470-0865

Establishment Registration: 2182979

Submitted: Friday, July 27, 2012

Device Name: TruScan® Surface Electrodes

Trade Name: TruScan® Surface Electrodes

Classification Name: 21 CFR 8823.1350, Cutaneous Electrode GXY

Classification: Class II

Common/Usual Name: Surface Electrode, Cutaneous Electrode

Predicate Device
Ambu, Inc (K032278)
Grass Instruments (Marketed prior to 1974)

Indication for Use

The PMT® TruScan® Surface Electrodes are indicated for cutaneous use in the general recording and monitoring of the Electroencephalograph (EEG) and Evoked Potential (EP).

The PMT® TruScan® Surface Electrodes are CT compatible and MR Conditional under the following conditions:

- Static magnetic field strength of 1.5-T only
- Maximum spatial gradient magnetic field of 5,000 Gauss/cm (50T/m) or less
- The connector hub must be placed near the center MR system's bore, and must be at least 20-cm from the wall of the MR system's bore at all times.

- The extension cable must be disconnected from the PMT TruScan Surface Electrode before scanning and MUST remain disconnected throughout the entire MR scan.
- Normal Operating Mode of operation for the MR system with a maximum whole body averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning (i.e., per pulse sequence)

Device Description

The PMT® TruScan® Surface Electrodes are non-invasive, cutaneous devices used in the acquisition of signals for the purpose of monitoring and recording Electroencephalograph (EEG) and Evoked Potentials (EP).

The reusable TruScan® Surface Electrodes have a disc with a diameter of 10 mm coated with silver / silver chloride (Ag/AgCl). Each disc is permanently adhered to an insulated lead wire. An extension cable is required to connect the TruScan® Surface Electrodes to the recording equipment. The extension cable is electrically insulated and terminated by a molded touch proof connector that is compliant to the safety requirements outlined in IEC 60601-1 subclause 56.3(c).

During a MRI examination, the extension cable must be disconnected from the TruScan® Surface Electrodes.

Numbered and color coated lead wires are provided to facilitate identification.

The electrodes are provided non-sterile and can be reused.

Technological Characteristics and Performance

Indications	*The PMT® TruScan® Surface Electrodes are indicated for cutaneous use in the general recording and monitoring of the Electroencephalograph (EEG) and Evoked Potential (EP).*
MR Conditions	*The PMT® TruScan® Surface Electrodes are CT compatible and MR Conditional under the following conditions:* • *Static magnetic field strength of 1.5-T only* • *Maximum spatial gradient magnetic field of 5,000 Gauss/cm (50T/m) or less* • *The connector hub must be placed near the center MR system's bore, and must be at least 20-cm from the wall of the MR system's bore at all times.* • *The extension cable must be disconnected from the PMT TruScan Surface Electrode before scanning and MUST remain disconnected throughout the entire MR scan.* *Normal Operating Mode of operation for the MR system with a maximum whole body averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning (i.e., per pulse sequence)*
Sensor Cup Construction	Silver/silver chloride
Cup Diameter	10 mm
Assembly to Cup	ABS/Carbon fiber composite
Lead Wire Core	Nichrome
Lead Wire Insulation	PVC

Electrode length	60" (electrode + cable)
Lead Wire Connection	1.5 mm Brass/Polypropylene IEC 60601-1 subclause 56.3(c) compliant
Packaging	Non-sterile, sealed in PE pouch or equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 19, 2012

PMT Corporation
c/o Mr. Al Iversen
President
1500 Park Road, PO Box 610
Chanhassen, MN 55317

Re: K122376
Trade/Device Name: PMT TruScan® MR Conditional Surface Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 10, 2012
Received: December 13, 2012

Dear Iversen:

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,

Victor Krauthamer -A

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 Form

510(k) Number (if known): K122376

Device Name: PMT® TruScan® Surface Electrode

Indications for Use

The PMT® TruScan® Surface Electrodes are indicated for cutaneous use in the general recording and monitoring of the Electroencephalograph (EEG) and Evoked Potential (EP).

The PMT® TruScan® Surface Electrodes are CT compatible and MR Conditional under the following conditions:

- Static magnetic field strength of 1.5-T only
- Maximum spatial gradient magnetic field of 5,000 Gauss/cm (50T/m) or less
- The connector hub must be placed near the center MR system's bore, and must be at least 20-cm from the wall of the MR system's bore at all times.
- The extension cable must be disconnected from the PMT TruScan Surface Electrode before scanning and MUST remain disconnected throughout the entire MR scan.
- Normal Operating Mode of operation for the MR system with a maximum whole body averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning (i.e., per pulse sequence)

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K122376