K082474

PMT Corporation
510(k) Summary

EXHIBIT 5

Submitter's Name, Address, and Date of Submission

Eric Caillé
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PMT Corporation
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Chanhassen, MN

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MAY - 8 2009

Submitted:

Device Name	PMT Subdural Cortical Electrodes
Trade Name:	PMT Subdural Cortical Electrodes (Dual Side Macro Electrodes, Dual Side Micro Electrodes, Dual Side Macro-Micro Electrodes, Dual Sided Hemispherical Macro Electrodes, Dual Sided Hemispherical Micro Electrodes, Dual Side Hemispherical Macro-Micro Electrodes, Macro Grids, Macro Strip, Macro-Micro Grids, Macro-Micro Strips, Micro Grids, and Micro Strips.)
Classification Name:	GYC, 21CFR882.1310
Common/Usual Name:	Electrode, Cortical

Predicate Device
Cortac Cortical Electrode (k964224)
AD-TECH Subdural Electrode (k053363)

Indication for Use
Catalog Numbers 2110-XXX: The Subdural Cortical Electrodes (Dual Side Macro Electrodes, Dual Side Micro Electrodes, Dual Side Macro-Micro Electrodes, Dual Sided Hemispherical Macro Electrodes, Dual Sided Hemispherical Micro Electrodes, Dual Side Hemispherical Macro-Micro Electrodes, Macro Grids, Macro Strip, Macro-Micro Grids, Macro-Micro Strips, Micro Grids, and Micro Strips.) are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals on the surface of the brain.

Device Description
PMT Subdural Cortical Electrodes (Dual Side Macro Electrodes, Dual Side Micro Electrodes, Dual Side Macro-Micro Electrodes, Dual Sided Hemispherical Macro Electrodes, Dual Sided Hemispherical Micro Electrodes, Dual Side Hemispherical Macro-Micro Electrodes, Macro Grids, Macro Strip, Macro-Micro Grids, Macro-Micro Strips, Micro Grids, and Micro Strips.)

The Subdural Cortical Electrode is used intraoperatively for monitoring recordable electrical brain activity. This invasive intracranial, subdural electrode recording is performed directly on the surgically exposed brain. This method is necessary when the seizure focus is too small and or too deep within the brain to produce a recordable EEG seizure. The Subdural Cortical Electrode strip and grid electrode are used in cases where it is necessary to establish a high degree of confidence in the electrical localization (foci), seizure frequency, severity type and other electro-clinical characteristics.

Macro Electrodes use 2mm, 3mm or 4.5mm diameter platinum circular recording discs. Micro Electrodes are single wires with the distal tip exposed and flush with the surface of the silicone. They are made of the same material used in the assembly of the Electrode. The Micro electrode allow for more precise definition of the Epileptic activity. They can be used solo or in combination with Macro recording discs.

The PMT device consists of one or more electrically conductive contacts. The model number 2110 indicates a platinum alloy wire and platinum alloy electrode contacts. The electrodes' contacts are molded into a silicone rubber matrix in a fixed pattern. Insulated wires extend from each electrode through a flexible silicone tube to connector for EEG monitoring.

The electrode material for the 2110-XXX is 90:10 platinum iridium

Technological Characteristics and Performance
The technological characteristics of the product are not affected in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

PMT Corporation
% Mr. Eric Caille
1500 Park Road
Chanhassen, Minnesota 55317

Re: K082474
Trade Name: PMT Subdural Cortical Electrodes
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: II
Product Code: GYC
Dated: April 22, 2009
Received: April 23, 2009

Dear Mr. Caille:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Daniel Krause

for Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT 3

Indications for Use Statement

510(k) Number (if known) K082474

Device Name

PMT Subdural Cortical Electrodes

Indications for Use

Catalog Numbers 2110-XXX: The Subdural Cortical Electrodes (Dual Side Macro Electrodes, Dual Side Micro Electrodes, Dual Side Macro-Micro Electrodes, Dual Sided Hemispherical Macro Electrodes, Dual Sided Hemispherical Micro Electrodes, Dual Side Hemispherical Macro-Micro Electrodes, Macro Grids, Macro Strip, Macro-Micro Grids, Macro-Micro Strips, Micro Grids, and Micro Strips.) are intended for temporary (<30 day) use with recording, monitoring, and stimulation equipment for the recording, monitoring and stimulation of electrical signals on the surface of the brain. *This device is restricted to the sale by or on the order of a physician.*

(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

(Optimal Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082474