- **Premarket Notification [510(k)] Summary**

Submitters name:	PMT CORPORATION
Submitters Address:	PMT Corporation 1500 Park Road Chanhassen, MN 55317
Phone:	(952) 470-0866
Fax:	(952) 470-0865
Contact name:	Eric Caillé
Date:	Tuesday, November 25, 2003
Trade name:	PMT Sphenoidal Electrode
Common name:	Sphenoidal Electrode
Classification name:	Electrode, Depth (per 21 CFR section 882.1330)

Substantial Equivalence claim:

The PMT Sphenoidal Electrode is substantially equivalent, for the purpose of this 510(K), to the Wyler Sphenoidal Electrode (K861031) manufactured by AD-Tech Medical.

Device Description:

The PMT Sphenoidal electrode consists of an insulated Platinum/Iridum or Stainless Steel wire with an exposed distal portion used to record EEG activity. The proximal end of the wire terminates in a connector. The connector attaches to an Interconnection cable external to the patient and connected to the EEG equipment.

The PMT Sphenoidal electrode is introduced to the recording site via an introducer. Once in place, the introducer is removed leaving the electrode available for recording EEG patterns from the inferior mesial temporal lobe.

The PMT Sphenoidal Electrode is provided sterile for single use and for Intraoperative use only.

Indications for Use:

The PMT Sphenoidal Electrode is indicated for Intraoperative recording of electrical signals for epilepsy monitoring at the surface and subsurface levels of the brain.

Summary of testing:

Mechanical tests confirm the equivalence to predicated devices. The biocompatibility testing will comply with ASTM, ANSI/AAMI standards.

Sterility:

The PMT Sphenoidal Electrode is manufacture in a clean room environment and is double bagged in Tyvek sterilization pouches. It is provided sterilized by the ethylene oxide method to provide a sterility assurance level (SAL) of 10^{-6}.

The PMT Sphenoidal Electrode is provided pyrogen free. The method of determination is the Limulus Amebocyte Lysate Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2004

Mr. Eric Caillé
Neuro Division General Manager
PMT Corporation
1500 Park Road
Box 610
Chanhassen, Minnesota 55317

Re: K033730
Trade/Device Name: PMT Sphenoidal Electrode and Accessory
Model 2101-31and 2102-31
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: II
Product Code: GZL
Dated: June 10, 2004
Received: June 14, 2004

Dear Mr. Caillé:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

510(k) Number (if known): K033730

Device Name: PMT SPHENOIDAL ELECTRODE AND ACCESSORY MODEL 2101-31 AND 2102-31

Indications For Use:

The PMT SPHENOIDAL Electrode is indicated for Intraoperative recording of electrical signals for Epilepsy monitoring at the surface and subsurface levels of the brain. It is not intended for long term monitoring.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K033730