DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PMT® Corporation
c/o Eric Caillé
General Manager
1500 Park Road
Chanhassen, MN 55317

JUL 28 2009

Re: K090733
Trade/Device Name: PMT Halo System
Regulation Number: 21 CFR 882.5960
Regulation Name: Skull Tongs for Traction
Regulatory Class: II
Product Code: HAX
Dated: June 22, 2009
Received: June 23, 2009

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 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.

EXHIBIT 3

Indications for Use Statement

510(k) Number (if known) K090733

Device Name
PMT Halo

Indications for Use

The PMT Halo System with Open Back Carbon Graphite and Titanium Skull Pins and the PMT Halo System with Closed Back Carbon Graphite and Titanium Skull Pins provide cervical immobilization necessary for healing and rehabilitation of cervical spinal cord injuries.

The PMT Halo system is MR Conditional and may be used safely in an MRI under the following conditions:

- Static magnetic field of 1.5T and 3T only
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Normal operating mode with a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning (per pulse sequence).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__
(Per 21 CFR 801.109

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

Over the Counter Use____

(Optional Format 1-2-96)

510(k) Number K090733

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

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