K080499

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magstim

Spring Gardens • Whitland
Carmarthenshire • Wales • UK
SA34 0HR

+44 (0) 1994 240798
+44 (0) 1994 240061
info@magstim.com
www.magstim.com

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850
04 December 2008

Contact information:

Anwen Evans (Ms)
The Magstim Company Ltd
Spring Gardens, Whitland
Carmarthenshire, Wales, UK
SA34 0HR
Tel: +44 (0) 1994 242902
Fax: +44 (0) 1994 240061
E-mail: anwen.evans@magstim.com

The product information is as follows:

Product:	Magstim Double 70mm Air Film Coil
Class:	Class CFR 882.1870
Panel:	Neurology
Product Code:	GWF

Classification name:	Stimulator, Electrical, Evoked Response
Common or usual names:	Cooled Coil
Proprietary name:	Magstim Double 70mm Air Film Coil

5.1 Description of the Device

The Magstim Double 70mm Air Film Coil is an air-cooled coil intended for peripheral stimulation of the nerves. This coil enables deep, and otherwise inaccessible, nerves to be

stimulated easily and relatively painlessly. Additionally, no skin preparation is required and stimulation can be achieved through clothing. The Magstim Double 70mm Air Film Coil is for use by, or under the supervision of, a medical practitioner only.

5.2 Intended Use of the Device

The Magstim Double 70mm Air Film Coil is a stimulating coil solely intended for use with the Magstim Rapid^2 Stimulating Unit for the purposes of peripheral nerve stimulation. The coil is an accessory of the Magstim Rapid^2 Unit.

5.3 Predicate Devices

The predicate devices used in this submission are:

- Magstim Double 70mm Remote Coil (reference K060847).
- Magstim 2nd Generation Double 70mm Coil (reference K051864).

5.3.1 Comparison with the predicate devices

	Magstim Double 70mm Air Film Coil (Subject Device)	**Magstim Double 70mm Remote Coil (Predicate Device)**	**Magstim 2nd Generation Double 70mm Coil (Predicate Device)**
Average inductance	12μH	16.35μH	15.50μH
Manner of stimulation	Peripheral	Peripheral	Peripheral
Cooling	Yes	No	No
Multiple use	Yes	Yes	Yes
Sterile	No	No	No
Weight	3kg	1.6kg	1.8kg
Integral adapter	Yes	No	No

5.4 Conclusions

The Magstim Double 70mm Air Film Coil is both safe and effective and is similar in its risks and benefits, as well as its manner of performance, to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Magstim Company Limited
% Ms. Anwen Evans
Spring Gardens, Whitland
Carmarthenshire, Wales
United Kingdom
SA34 0HR

DEC 0 8 2008

Re: K080499
Trade/Device Name: Magstim® Double 70mm Air Film™ Coil
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: November 20, 2008
Received: December 1, 2008

Dear Ms. Evans:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K_____

Device Name: Magstim® Double 70mm Air Film™ Coil

Indications for Use:

The Magstim® Double 70mm Air Film™ Coil is a stimulating coil solely intended for use with the Magstim® Rapid² Stimulating Unit for the purposes of peripheral nerve stimulation. The coil is an accessory of the Magstim® Rapid² Unit.

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)

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

510(k) Number K080499