K051864

DEC 2 1 2005

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510(K) SUMMARY

Magstim Company Ltd – Magstim Rapid^2 and Magstim Super Rapid^2

Preparer/ Contact Anthony Thomas
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Manufacturer **Magstim Company Limited**

Date Summary was prepared: June 16th 2005
Name of the Device: Magstim Rapid^2 and Magstim Super Rapid^2

Identification of predicate device(s): Magstim Rapid K992911
Cadwell High Speed Magnetic Stimulator K905059
Dantec Mag Pro K926516

Description of the device and modifications:

This submission is being made because the Magstim Company, referred to as Magstim, has modified the device marketed under K992911 to replace the external computer with an embedded microcontroller. User interface with the system is via a bespoke touch-screen display module. Previously, a laptop interfaced with the main unit via the PCMCIA Port of the computer. The new system architecture means that there is dedicated, in-house, software controlling the system, resulting in it no longer requiring an external laptop or Microsoft Windows operating environment. The currently marketed Magstim Rapid also requires two and four booster modules, which has been replaced with single and dual module power supplies in the Rapid^2. 2nd generation coils and remote control coils are also introduced with this 510(k), however, the original Magstim Rapid coil family in K992911 can be used with the Rapid^2, and the differenced between the 2nd generation and the original coils do not raise issues of safety and effectiveness. The intended use of the Magstim Rapid^2 and Magstim Super Rapid^2 is the same as in K992911, and the frequency output has been changed from 50Hz to 60Hz with similar power levels, which is consistent with the Cadwell High Speed Magnetic Stimulator in K905059.

Intended Use: Stimulation of Peripheral Nerves.

Substantial Equivalence:

Parameter	**Magstim Rapid^2 & Magstim Super Rapid^2**	**K992911**
Field Strength	1.2 Tesla for Double 70mm Coil supplied with System.	1.2 Tesla (depends on coil type and power level)
Super Frequency	60Hz (Magstim Super Rapid^2)	50Hz (Super Rapid)
Frequency	36Hz (Magstim Rapid^2)	25Hz (Rapid)
Frequency Resolution	1Hz Steps (user controllable)	1Hz Steps (User controllable)
Train Duration	Up to 10 Seconds depending on frequency and coil	Up to 10 seconds depending on frequency and coil
Train Resolution	0.1 seconds	0.1 seconds
Single Stimulus Mode	Yes	Yes
Interpulse Spacing	Up to 250 stimuli per stimulus train	Up to 250 stimuli per stimulus train
Number of Stimuli	Up to 250 stimuli per stimulus train	Up to 250 stimuli per stimulus train
Coil Temperature	5-40°C Operating Range	5-40°C Operating Range

60Hz Comparison

Parameter	Magstim Rapid^2/ Magstim Super Rapid^2	Caldwell High Speed Magnetic Stimulator K905059
36Hz/60Hz	Max 30% of power/ Max 37% of power	Unknown/ Max 40% of power
100% Power	11Hz/22Hz	25Hz

Software documentation and testing, environmental and EMC testing, as well as magnetic field plots and acoustic output measurements where provided to demonstrate safety and performance.

Conclusion

The modified device, the Magstim Rapid^2 (Magstim SuperRapid^2) is substantially, equivalent to the Magstim Rapid (Magstim Super Rapid) and the Caldwell High Speed Magnetic Stimulator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2005

Mr. Anthony Thomas
The Magstim Company Limited
Spring Gardens, Whiteland
Carmarthenshire, Wales
UNITED KINGDOM

Re: K051864
Trade/Device Name: Magstim Rapid2, Magstim Super Rapid2
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF
Dated: November 21, 2005
Received: November 21, 2005

Dear Mr. Thomas:

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 (240) 276-0115. 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,

Mark Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Revised

Indications for Use

510(k) Number (if known): K051864
Device Name: Magstim Rapid^2, Magstim Super Rapid^2
Indications For Use: Peripheral Nerve Stimulation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucklew for MXM

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

510(k) Number K051864