K130403

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 C.F.R. §807.92.

The submitter of this premarket notification is:

J. P. Ouellette
Principal
Custom Microbiology Associates
101 Milk Street
Methuen, Massachusetts
01844
Tel: (978) 682-8085
Fax: (207) 912-8085
e-mail: jpouellette01@gmail.com

AUG 2 3 2013

Date of summary: March 19, 2013

Device name: D70^2 Coil

Common name: Evoked Response Electrical Stimulator

Classification names

Regulation Number	ProCode	Classification Name
882.1870	GWF	Evoked Response Electrical Stimulator

Device Description: The Magstim D70^2 coil is designed for use with the Magstim 200^2 stimulator or the Magstim Rapid^2 stimulator. The Magstim D70^2 coil provides a method of non-invasively delivering its output to a target such as the peripheral nerves. Discharge current through the coil generates a brief, high intensity magnetic pulse. When the coil is applied to a conductive medium such as the human body, eddy currents are produced in the medium by electromagnetic induction. This stimulation method enables deep and otherwise inaccessible nerves to be stimulated easily and relatively painlessly. In addition, no skin preparation is required and stimulation can be achieved through clothing. The coil is a non-sterile reusable device intended for multi-patient use. The coil is transportable and is intended to be used in a laboratory, consulting room or equivalent environment. The coil is intended for short-term patient contact where single or cumulative contact does not exceed 24 hours.

Predicate Devices: This device is substantially equivalent to the current Magstim Model 200^2 with Double 70mm Remote Coil (K060847) and the Magstim Model Rapid2 with Double 70mm Remote Coil (K051864).

Modifications	The primary modification to this device is the overlapping windings in the coil resulting in improved achievement of motor thresholds with less stimulator output.
Intended Use	The modified device has the same intended use as the legally marketed predicate devices. The Magstim D70^2 coil is a stimulating coil intended for use with the Magstim 200^2 Stimulating Unit or the Magstim Rapid^2 Stimulating Unit for the purpose of peripheral nerve stimulation for diagnostic purposes. The coil is an accessory to the Magstim 200^2 Stimulating Unit and the coil is an accessory to the Magstim Rapid^2 Stimulating Unit.
Technological characteristics	The modified device has the same technological characteristics as the legally marketed predicate devices.
Testing	Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device and to assess any of the differences between the subject device and the predicate device. Testing involved safety testing from the risk analysis, including laboratory studies for electrical safety testing, EMC testing, usability testing for consumer accuracy as well as magnetic field measurement testing. Acceptance criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.
Standards	The Magstim Model 200^2 with D70^2 coil and the Magstim Model Rapid^2 with D70^2 coil were designed to comply with the applicable portions of the following product standards: 1. IEC 60601-1:1998 2. IEC 60601-1-2:2007 3. ISO 10993-1:2009
Conclusion	This device is substantially equivalent to the predicate device and does not present any new issues of safety or effectiveness. The intended use of the modified device, as described in its labeling, has not changed from that of the predicate device as a result of the modifications. The only difference between the subject device and the predicate device were qualified with appropriate testing. The fundamental scientific technology employed in the operation of this device has not changed from the predicate device.

5.0 Substantial Equivalence

5.1 Similarities and Differences The similarities and differences between the predicate and subject device are listed in Table 5.1.

Table 5.1 Comparison of Similarities and Differences

Comparative Characteristic	**Subject Device Magstim D70² Coil P/N 4102-00**	**Predicate Device Magstim 2nd Generation Double 70mm Coil P/N 3191-00 (Reference K060847)**	**Predicate Device Magstim 2nd Generation Double 70mm Coil P/N 3191-00 (Reference K051864)**
Intended Use	The Magstim D70² coil is a stimulating coil intended for use with the Magstim 200² Stimulating Unit or the Magstim Rapid² Stimulating Unit for the purpose of peripheral nerve stimulation for diagnostic purposes. The coil is an accessory to the Magstim 200² Stimulating Unit and the coil is an accessory to the Magstim Rapid² Stimulating Unit.	The Magstim Model 200² is a magnetic nerve stimulator intended for the purpose of peripheral nerve stimulation for diagnostic purposes.	The Magstim Model Rapid², Magstim Super Rapid² is indicated for stimulation of peripheral nerves
Indications for Use	The Magstim D70² coil is a stimulating coil intended for use with the Magstim 200² Stimulating Unit or the Magstim Rapid² Stimulating Unit for the purpose of peripheral nerve stimulation for diagnostic purposes. The coil is an accessory to the Magstim 200² Stimulating Unit and the coil is an accessory to the Magstim Rapid² Stimulating Unit.	The Magstim Model 200² is a magnetic nerve stimulator intended for the purpose of peripheral nerve stimulation for diagnostic purposes	The Magstim Model Rapid², Magstim Super Rapid² is indicated for stimulation of peripheral nerves
Average inductance	13μH	15.50μH	15.50μH
Number of Turns	11	9	9

Number of Windings	2		2	2
Wire Cross Sectional Area [1]	12.5 mm^2		9 mm^2	9 mm^2
Coil Cable Length	1.8m		2.0m	2.0m
Manner of stimulation	Peripheral		Peripheral	Peripheral
Peak Magnetic Field	2.1T [2] (Magstim 200²)	1.2T (Magstim Rapid²)	1.7T [2]	1.2T
Number of pulses the coil can be operated at 80% stimulator output before reaching maximum operating temperature [1]	>290 (Magstim 200²)	>600 (Magstim Rapid²)	110	110
Cooling	No		No	No
Multiple Use	Yes		Yes	Yes
Sterile	No		No	No
Weight	1.95kg		1.8kg	1.8kg
Integral adapter	Yes		No	No

Notes:

(1) Larger cross sectional wire area reduces resistance and heat generation. As a result the coil can run longer before warming up. This does not mean it will be used to deliver more stimuli; the number of stimuli delivered is ultimately up to the physicians conducting the test.

(2) Peak magnetic field strengths were measured using a very thin magnetic field probe (0.8mm) in order to get as close to the coil surface as possible. Since magnetic field strength reduces with distance away from a coil, probe size does affect the measurement outcome. At typical stimulation depths magnetic field figures are, therefore, lower.

5.2 Predicate devices

The predicate device is the Magstim 2nd Generation Double 70mm Coil p/n 3191-00 evaluated with the Magstim Rapid² TMS unit in K051864 and with the Magstim 200² TMS unit in K060847.

5.3 Similarities

The subject device and the predicate device are similar with respect to respect to indications for use and intended use, fundamental scientific technology as well as the number of windings, the lack of the need for cooling, the ability to be used multiple times and are limited to peripheral stimulation only.

5.4 Differences

The subject device and the predicate devices are different due to the overlapping of the windings in the D70^{2}coil (P/N 4102-00) which results in improved achievement of motor thresholds with less stimulator output. This design feature also manifests different values for peak magnetic field and pulses generated when the subject device is used with one or the other stimulating unit. When the subject device is used with the Magstim Rapid^2, more pulses are generated than with the Magstim 200^2 until the peak temperature is achieved and the coil shuts down, This design feature allows the practitioner the flexibility to use the D70^2 coil and the Magstim Rapid^2 for a longer period until the peak temperature is achieved and the coil shuts down. When the subject device is used with the Magstim 200^2, a slightly higher peak magnetic field value is achieved on the coil surface. This is due to the higher efficiency of the coil as well as the thickness of the plastic cover and the inner coil insulation of the subject device. Peak magnetic field figure of 2.1 tesla is below that used inside 3 tesla MRI scanners.

5.5 Conclusion

Based upon the analysis of the similarities and differences, the Magstim D70^2 Coil as described in this 510(k) is substantially equivalent to the predicate device and does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 23, 2013

The Magstim Company Limited
c/o Mr. J.P. Ouellette,
Custom Microbiology Associate
101 Milk Street
Methuen, MA 01844

Re: K130403
Trade/Device Name: D70^2 coil
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: July 8, 2013
Received: July 11, 2013

Dear Mr. Ouellette:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

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 Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130403

Device Name: D70^2 Coil

Indications For Use:

The Magstim D70^2 coil is a stimulating coil intended for use with the Magstim® 200^2 Stimulating Unit or the Magstim® Rapid^2 Stimulating Unit for the purpose of peripheral nerve stimulation for diagnostic purposes. The coil is an accessory to the Magstim ® 200^2 Stimulating Unit, and the coil is an accessory to the Magstim® Rapid^2 Stimulating Unit.

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-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.08.23 15:37:34 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _ K130403