510(k) Summary

OCT 3 1 2006

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum Denmark
Phone:	+45 4499 8444
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Contact:	Lise Terkelsen
Preparation date:	August 31, 2006
Trade name:	MagPro R30
Common name:	MagPro R30
Classification name:	Evoked Response Electrical Stimulator
Identification of predicate devices:	MagPro, K926516 Magstim Super Rapid², K051864

Device description
MagPro R30 is a Magnetic stimulator used for Magnetic stimulation.
Magnetic stimulation is a non-invasive technique for stimulating neural tissue.
Application areas of magnetic stimulation are a sub-set of the application areas for current stimulation.

The MagPro R30 is connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue. The original coils MC-125 and MC-B70 in K926516 can be used with the MagPro R30 as well as the coils C-100, C-B60 and MMC-140-II.

The MagPro R30 consists of power electronics to generate the magnetic field in the Magnetic Coil. The MagPro R30 is controlled via a simple user interface, enabling the operator to overview all functions, stimulus sequences, controls, status and measured data. The MagPro R30 has a built-in computer and a 8.4" display.
The magnetic pulse is Biphasic waveform and the stimulator can stimulate with a frequency of up to 30 pulses per second (pps).

Intended Use:
The MagPro R30 is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Substantial Equivalence:
The MagPro R30 in this submission has the same characteristics as the predicate devices, MagPro (K926516) and Magstim Super Rapid² (K051864). Stimulation of peripheral nerves is the intended application which applies for all three devices.

They consist of a unit comprising power electronic to generate the magnetic fields in a Magnetic Coil. All includes a user interface to control the device via knobs and a display on the front panel.

The waveforms for the MagPro R30 and the Magstim Super Rapid² are biphasic, for the MagPro the waveforms are biphasic and monophasic. The Max. stim. frequency is 30 pulses per second for MagPro R30 and Magpro, while for the Magstim Super Rapid² the frequency is 60 pulses per second.

The realized magnetic field the stimulator is produced together with the connected coil, is comparable to the old MagPro in K926516. The mechanical, electrical and magnetic parameters of the coils in this submission are very near to the parameters of the predicate coils. All coils are based on the same technology, design and material used.

The MagPro R30 is CE-marked and complies with the Medical Device Directive 93/42/EEC. The MagPro R30 is developed and manufactured according to EN13485, "Medical devices – Quality management systems – Requirement for regulatory purposes". The MagPro R30 complies with the standard for electrical safety standard, IEC 60601-1, and has been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2.

Conclusion:
The MagPro R30 has the same intended use as the predicate devices and the same technological features.

All coils are a variant to the original approved in K926516.

The clinical performance of the magnetic field to the patient is unchanged from the predicate coils to the proposed coils.

The MagPro R30 and coils do not raise new issues of safety and effectiveness and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lise Terkelsen
Tonica Elektronik A/S
Lucernemarken 15
DK-3520 Farum
Denmark

OCT 3 1 2006

Re: K061645
Trade/Device Name: MagPro R30 Magnetic Stimulator used with Model MC-125, MC-B70, C-100, C-B60, and MMC-140-II Coils
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: September 19, 2006
Received: September 22, 2006

Dear Ms. Terkelsen:

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) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its 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): K061645

Device Name: MagPro R30

Indications for Use: The device is intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Prescription Use ___X___ Over-The-Counter Use _____

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

510(k) Number K061645