K091940

510(k)

MagPro R30 incl. MagOption, X100, X100 incl. MagOption

510(k) Summary

MAR 2 6 2010

Name of 510(k) owner:	Tonica Elektronik A/S Lucernemarken 15 DK-3520 Farum Denmark
Phone: Fax:	+45 4499 8444 +45 4499 1544
Contact:	Lise Terkelsen
Preparation date:	June 19, 2009
Trade name:	MagPro R30 incl. MagOption MagPro X100 MagPro X100 incl. MagOption
Common name:	MagPro R30 incl. MagOption MagPro X100 MagPro X100 incl. MagOption
Classification name:	Evoked Response Electrical Stimulator
Identification of predicate devices:	MagPro R30, K061645 MagPro, K926516 Magstim Super Rapid², K051864 Keypoint (K944547) Digitimer DS7A (K051357)

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Device description

MagPro R30 incl. MagOption, MagPro X100 and MagPro X100 incl. MagOption are Magnetic stimulators used for Magnetic stimulation. These three devices are, together with the predicate device MagPro R30, called "MagPro Family". Hereafter we name the three devices in this submission "the new devices".

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 new devices are connected to a Magnetic Coil which transfers the magnetic stimulation to the tissue. All Standard coils as well as the Fluid and Cool coils can be used with the MagPro devices, (K926516, K061645, K071821).

The new devices are magnetic stimulators, featuring Biphasic, Monophasic, Halfsine, Biphasic Burst waveform, stimulation rates up to 100 pulses per second (pps), stimulus sequences and protocols controlled via a built-in computer and 8,4" display.

Intended Use:

The magnetic stimulators are intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Substantial Equivalence:

The new devices in this submission have the same characteristics as the predicate devices, MagPro R30 (K061645), MagPro (K926516) and Magstim Super Rapid² (K051864). Stimulation of peripheral nerves is the intended application which applies for all these magnetic stimulator 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 or touch screen and a display on the front panel.

The difference in performance between the new devices and the predicate devices are thoroughly compared and discussed in the "Substantial Equivalence" section. Evidence for the higher repetition rate of 100pps is documented and found substantial equivalent to current stimulators, Keypoint (K944547) and Digitimer DS7A (K051357), which are able to perform at more powerful repetition rates.

The new devices are CE-marked and comply with the Medical Device Directive 93/42/EEC and also the Canadian CMDR. The new devices are developed and manufactured according to EN13485, "Medical devices – Quality management systems – Requirement for regulatory purposes". The new devices comply with the standard for electrical safety standard, IEC 60601-1, and have been tested at a certified test center, UL Demko. EMC testing has been performed for compliance with the EMC standard, IEC 60601-1-2. The MagPro devices fulfill the requirements in the standard IEC 60601-1-6 Usability.

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Conclusion:
The MagPro R30 incl. MagOption, MagPro X100 and MagPro X100 incl. MagOption have the same intended use as the predicate magnetic stimulator devices and the same technological features. The difference in performance is shown equivalent to various predicate devices.

The new devices do not raise new issues of safety and effectiveness and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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

MAR 2 6 2010

Re: K091940
Trade/Device Name: MagPro R30 with Magoption, MagPro X100, and MagPro X100 with MagOption
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: March 15, 2010
Received: March 18, 2010

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. 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 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/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,

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

510(k) number: K091940

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
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For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page

Drafted: Joseph Hutter, Ph.D.
Edited:
Final:
Typed: Marisol Lendor, March 25, 2010

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Indications for Use

510(k) Number (if known):

Device Name:	MagPro R30 with MagOption MagPro X100 MagPro X100 with MagOption
Indications for Use:	The devices are intended to be used for stimulation of peripheral nerves for diagnostic purposes.

Prescription Use ___X___ and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

JOE HUTTER

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

510(k) Number K091940