K071821

JUL 27 2007

## 510(k) Summary

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| Name of 510(k) owner: | Tonica Elektronik A/S<br>Lucernemarken 15<br>DK-3520 Farum<br>Denmark |
| Phone: | +45 4499 8444 |
| Fax: | +45 4499 1544 |
| Contact: | Lise Terkelsen |
| Preparation date: | June 25, 2007 |
| Trade name: | MCF-B65, MCF-75, MCF-125, Cool-B65 |
| Common name: | MCF-B65, MCF-75, MCF-125, Cool-B65 |
| Classification name: | Evoked Response Electrical Stimulator |
| Identification of predicate devices: | K061645: MC-125, MC-B70, C-100, C-B60, MMC-140-II |

**Device description**
The coils MCF-B65, MCF-75, MCF-125 and Cool-B65 are used as an accessory together with a Magnetic stimulator used for magnetic stimulation. The coils transfer the magnetic stimulation to the tissue.

All four coils are constructed the same way. A coil winding element encapsulated in a plastic housing. The coil winding element is inside the housing surrounded by a liquid cooling media. The cooling media absorb the heat built up during use. The coil Cool-B65 is furthermore connected to an external Coil Cooler unit that generates an active circulation of the cooling media, which allows the coil to operate for an even longer period.

They are either circular or butterfly shaped. They are from 65 to 125 mm in diameter.

**Intended Use**:
The coils are intended for stimulation of peripheral nerves.

**Substantial Equivalence**:
The coils in this submission has the same characteristics as the predicate coils (K061645), Stimulation of peripheral nerves is the intended application which applies for the 5 cleared coils as well as the 4 modified coils. In size, shape and application they are all comparable.

All coils (both cleared and modified) have a built-in thermo sensor to measure the temperature of the coil surfaces to prevent high temperature on the patient skin or operator.

The coil winding element of the predicate coils are surrounded by molding material, where as the modified coils are surrounded by a liquid cooling media. The magnetic field is not affected by the modification.

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

**Conclusion**:
The MCF-B65, MCF-75, MCF-125 and Cool-B65 have the same intended use as the predicate coils and the same technological features. The modified coils do not raise new issues of safety and effectiveness and are substantially equivalent to the predicate coils.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 27 2007

Re: K071821
Trade/Device Name: Coils, Models MCF-B65, MCF-75, MCF-125, Cool-B65
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: June 28, 2007
Received: July 3, 2007

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.

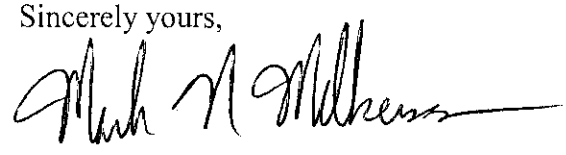
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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 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 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):

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| Device Name: | Coils:<br>MCF-B65, MCF-75, MCF-125, Cool-B65 |
| 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 K071821