K062437

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Attachment D:

510(k) Summary

Manufacturer:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands
Submitted by:	Technomed Europe Amerikalaan 71 6199 AE Maastricht Airport The Netherlands Tel.: (+31) 43-408 6868 Fax: (+31) 43-408 6888
Contact person:	René Roncken Manager Quality Assurance E-mail: rroncken@technomed.nl
Date:	December 22, 2006
Proprietary Name:	Diagnostic electromyography needle electrode
Common/usual Name:	Disposable hypodermic EMG needle electrode
Classification Name: 890.1385)	Diagnostic electromyography needle electrode (21 CFR section
Substantial Equivalence:	K973444: Teca Myoject disposable needle electrode K002992: Medtronic Disposable Hypodermic Needle Electrode
Device description:	The disposable hypodermic EMG needle electrode is designed for single use only. It consists of a stainless steel cannula electrically insulated with a PTFE coating, except for the lancet point and the inner surface of the tube. The coating is to ensure easy skin penetration and to ensure electrical insulation on the entire cannula, except for the point. A husk fitting together with a wire with connection to an extension cable has been attached to the cannula. This cable will enable the electrical signal to be transferred to a stimulating or recording device.
Intended Use:	The disposable hypodermic EMG needle electrode is used for muscle stimulation, motor unit action potential recording and drug delivery. The motor nerves are monitored by detecting EMG activity in the muscles they innervate. The drug used should be Botox Botilium Toxin type A. Note: Technomed Europe does not supply any drugs with the Disposable hypodermic EMG needle electrodes nor does Technomed Europe offer for sale any form of drugs.

Comparison to predicates:	The design, materials, chemical composition, packaging and other technological characteristics of the subject device is equivalent to those of the predicate devices.
Non-clinical data:	Technomed Europe has been bench testing the Disposable hypodermic EMG needle electrode to confirm performance characteristics of this device.
Conclusion:	The comparison to the predicate devices demonstrate that the Disposable hypodermic EMG needle electrode is safe and effective 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

Technomed Europe
% Mr. Rene Roncken
Manager Quality Assurance
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

FEB 16 2007

Re: K062437
Trade/Device Name: Disposable Hypodermic EMG Needle Electrode
Regulation Number: 21 CFR 890.1385
Regulation Name: Electromyograph Needle Electrode
Regulatory Class: Class II
Product Code: IKT
Dated: January 22, 2007
Received: January 25, 2007

Dear Mr. Roncken:

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" (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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.

Indications for Use

510(k) Number (if known): K062437

Device Name: Disposable hypodermic EMG needle electrode

Indications For Use:

The disposable hypodermic EMG needle electrode is used for muscle stimulation, motor unit action potential recording and drug delivery.
The motor nerves are monitored by detecting EMG activity in the muscles they innervate.

The drug used should be Botox Botilium Toxin type A.

Note: Technomed Europe does not supply any drugs with the Disposable hypodermic EMG needle electrodes nor does Technomed Europe offer for sale any form of drugs.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

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

510(k) Number K062437