MAY - 5 2005 K050395

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
Contact person:	René Roncken Manager Quality Assurance Tel.: (+31) 43-408 6868 Fax: (+31) 43-408 6888 E-mail: rroncken@technomed.nl
Date:	February 7, 2005
Proprietary Name:	Needle electrodes
Common/usual Name:	Disposable probe
Classification Name:	Needle electrode (21 CFR section 882.1350)
Substantial Equivalence:	K991583: Neurosign 400, 4 channel motor nerve monitor K980148: Neurosign 800, 8 channel motor nerve monitor K964869: Neurosign 800, 8 channel motor nerve monitor
Device description:	There are three types of disposable probes: Concentric, Bipolar and Monopolar Disposable Concentric probe The Concentric probe is very precise and has a diameter of only 1 mm. They are especially useful when working with the microscope, and allow the surgeon to differentiate between cranial nerves, to stimulate within the Internal Auditory Canal, or to stimulate fine fibers of the extra-cranial nerve without stimulating surrounding tissue. Disposable Bipolar probe The Bipolar probe has both the active and return electrode builds in to the probe. Both tips of the Bipolar probe must come into contact with tissue in order for the stimulation current to flow. The Bipolar probe will stimulate through a small amount of tissue. The Bipolar probe may be used in skull-base surgery and those involving peripheral motor nerves.

Disposable Monopolar probe

The Monopolar probe has a single active electrode, but must have a remote return electrode connected to the patient.

The Monopolar probe is insulated to a tip free coating length of 2 mm, so it is capable of very precise stimulation. The probe should be touched onto the tissue until the nerve is located. The Monopolar probe is designed to be used to stimulate the tumor mass or when a large spread is required.

Intended Use:

The stimulating probe is used:

- to locate and identify cranial motor nerves during ENT and intra-cranial procedures
- to locate and identify cranial and peripheral motor nerves during surgery, including spinal nerve roots
- to locate, identify and monitor cranial motor nerves during surgery

The motor nerves are monitored by detecting EMG activity in the muscles they innervate

Technological characteristics:

The design, materials, chemical composition, packaging and other technological characteristics of the subject devices are considered to be the equivalent of the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Ms. René Roncken
Manager Quality Assurance
Technomed Europe
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Re: K050325
Trade/Device Name: Disposable probe
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle electrode
Regulatory Class: II
Product Code: GXZ
Dated: March 22, 2005
Received: March 25, 2005

Dear Ms. 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) 276-0115 . 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K050325

Device Name: Disposable probe

Indications For Use:

The disposable probe is used:

- to locate and identify cranial motor nerves during ENT and intra-cranial procedures
- to locate and identify cranial and peripheral motor nerves during surgery, including spinal nerve roots
- to locate, identify and monitor cranial motor nerves during surgery

The motor nerves are monitored by detecting EMG activity in the muscles they innervate.

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)

Division of General, Restora[illegible]

K050325