K063729

Attachment D:

510(k) Summary

AUG 2 1 2007

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:	Maurice Roost Manager R&D Tel.: (+31) 43-408 6868 Fax: (+31) 43-408 6888 E-mail: mroost@technomed.nl
Date:	July 10, 2007
Proprietary Name:	Needle electrodes
Common/usual Name:	Disposable probe for stimulating electrode
Classification Name:	Needle electrode (21 CFR section 882.1350)
Substantial Equivalence:	K062996: Disposable probe for pedicle hole stimulation

Disposable pedicle screw probes are used as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring. The disposable pedicle screw probes are supplied sterile and are for single use only. The disposable pedicle screw probes are connected to an electrical stimulator using a flexible lead wire and a "touch-proof" safety connector on the distal end. Disposable pedicle screw probes require a separate stimulator return electrode. Disposable pedicle screw probes are used by the surgeon to locate and identify spinal nerve roots and to assess nerve function. The disposable pedicle screw probes are designed with a plastic handle and stainless steel active electrode shaft insulated to the tip. The disposable pedicle screw probes shaft may be bent to allow viewing access under a microscope.

Technomed Europe Disposable pedicle screw probes consist of an insulated probe shaft mounted to plastic handle. The probe shaft is electrically connected to a DIN 42802 "touch-proof" safety connector on the other end. The electrode is supplied in a sterile pouch.

Intended Use:	To locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

Comparison to predicates:	The design, materials, chemical composition, packaging and other technological characteristics of the subject devices are equivalent to those of the predicate devices.
Non-clinical data:	Technomed Europe has been bench testing the Disposable pedicle screw probe for stimulating electrode to confirm performance characteristics of this device.
Conclusion:	Technomed Europe Disposable pedicle screw probes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised or evident.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2007

Technomed Europe
% Mr. Maurice Roost
Manager R & D
Amerikalaan 71
Maastricht Airport, Limburg 6199 AE
The Netherlands

Re: K063729
Trade/Device Name: Disposable Pedicle Screw Probe, Model 3603-00
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: July 10, 2007
Received: July 16, 2007

Dear Mr. Roost:

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.

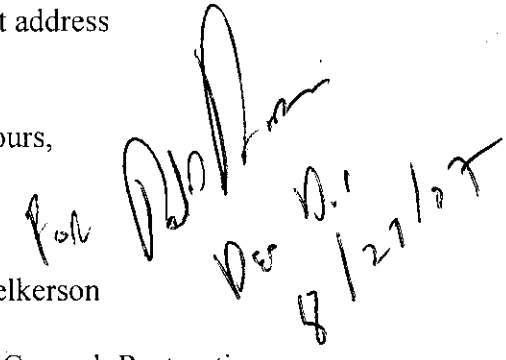
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

2. Statement Indications for Use

510(k) Number (if known): _____

Device Name: Disposable pedicle screw probe, Model 3603-00

July 10, 2007

Indications for Use:

The disposable pedicle screw probe is used to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE OMN ANOTHER PAGE IF NEEDED)

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

510(k) Number k063729

Prescription Use _X__ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)