MAY 26 2011

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:	Mr. Pierre Vreuls Manager Regulatory Affairs and Quality Assurance E-mail: pvreuls@technomed.nl
Date:	February 11, 2011
Proprietary Name:	Kartush Disposable Surgical stimulators
Common/usual Name:	Surgical nerve stimulator/locator
Classification Name:	Surgical nerve stimulator/locator is classified as class II per 21 CFR section 874.1820. Product code ETN.
Substantial Equivalence:	K031003: Medtronic Xomed Stimulus/Dissection Instruments, Ball-Tip Probes
Device description:	Kartush Disposable surgical stimulators are invasive devices used in the tissue dissection and monopolar stimulating. The instruments have different tip shapes for performing different dissection and stimulating procedures. The tip, tapered shaft, handle and connection pin are made of 1 pieces material. The instruments are designed for single-patient/multiple application use. The detachable lead wire has a safety DIN 42802 connector.

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Name and model numbers new devices:

Predicate device Medtronic Xomed [K031003]	**Technomed Europe surgical stimulators [proposed device]**	**New model numbers [proposed device]**
Medtronic Xomed name	**Proposed device name**	**Internal model #**
KSD Curved needle	Kartush Curved needle	42301-001
KSD Elevator	Kartush Elevator	42302-001
KSD Ring dissector, 3mm thin	Kartush Ring dissector, 3mm thin	42303-001
KSD Ring dissector, 2mm thin	Kartush Ring dissector, 2mm thin	42303-002
KSD Sickle knife	Kartush Sickle knife	42304-001
KSD 90° hook	Kartush 90° hook	42305-001
KSD Crabtree	Kartush Crabtree	42306-001
KSD Ring dissector, 3mm reg.	Kartush Ring dissector, 3mm reg.	42303-003
KSD Ring dissector, 2mm reg.	Kartush Ring dissector, 2mm reg.	42303-004

Extension cable to connect device to appropriate equipment:

Predicate device Medtronic Xomed [K031003]	**Technomed Europe surgical stimulators [proposed device]**	**New model numbers [proposed device]**
Medtronic Xomed name	**Proposed device name**	**Internal model #**
KSD connection lead wire	Kartush 3m extension cable DIN 42802 to DIN 42802	42307-001

Needle electrode already released under 510(k) K990015 (no predicate needed):

Description	**Device Name**	**Internal model #**
Needle electrode	Disposable subdermal needle electrode	40072-001

Commercial sets planned with above products:

New catalog numbers set	**Technomed Europe surgical stimulators**	**New model numbers**
Proposed catalog # set	**Proposed device name**	**Internal model #**
4007-00-KT	Kartush Curved needle	42301-001
	Kartush Elevator	42302-001
	Kartush Ring dissector, 3mm thin	42303-001
	Kartush 3m extension cable DIN 42802 to DIN 42802	42307-001
	Disposable subdermal needle electrode	40072-001
4009-00-KT	Kartush Ring dissector, 2mm thin	42303-002
	Kartush Sickle knife	42304-001
	Kartush 90° hook	42305-001
	Kartush Crabtree	42306-001
	Kartush Ring dissector, 3mm reg.	42303-003
	Kartush Ring dissector, 2mm reg.	42303-004
	Kartush 3m extension cable DIN 42802 to DIN 42802	42307-001
	Disposable subdermal needle electrode	40072-001

Intended.Use: The Technomed Europe Kartush disposable surgical stimulators are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

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 Kartush disposable surgical stimulators to confirm performance characteristics of this device. The bench testing consisted of dimensional measurements to determine the current density, impedance tests of the tips of the devices through saline, material comparison and dielectric strength test of the shaft and handle insulation. The conclusion of these bench tests is that the subject devices are equivalent to the predicate devices.

Comparison of characteristics between Kartush disposable surgical stimulators and the predicate device:

Characteristic	**Predicate device Medtronic Xomed [K031003]**	**Technomed Europe's Kartush disposable surgical stimulators [proposed device]**
Indications for use	Tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery including spinal nerve roots.	Same
Base material	Stainless steel	Same
Electrical insulation	Electrical insulation on all surfaces not intended to provide electrical contact with the patient and connection	Same
Distal patient contact surface material	Stainless steel	Same
Proximal stimulator connector	Yes	Yes
IEC 60601-1 protected pin design	Touch proof connector	Same
Patient contact material	Biocompatible	Same
Use and delivery	Single use and sterile	Same

Conclusion: The comparison to the predicate devices demonstrate that the Kartush disposable surgical stimulators are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 26 2011

Technomed Europe
c/o Pierre Vreuls
Manager Regulatory Affairs
Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Re: K110422
Trade/Device Name: Kartush Disposable Surgical Stimulators
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical nerve stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: April 18, 2011
Received: April 21, 2011

Dear Mr. Vreuls:

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

Indications for Use

510(k) Number (if known): K110422

Device Name: Kartush disposable surgical stimulators

Indications For Use:

The Kartush disposable surgical stimulators are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.

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)

Prescription Use X John Doucet
(Per 21 CFR 801.109)

John Doucet

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

510(k) Number K110422