K100912

KIRWAN® SURGICAL PRODUCTS

AUG 19 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

{as required by 21 CFR, section 807.92(c)}

FOR

Kirwan Disposable Nerve Stimulator Probes

Models: 41-3400, 41-3401, 41302, and 41-3403.

Common name: Disposable Nerve Stimulating Probe / Electrode.

Classification name: Needle electrode (§882.1350)

Product code: GXZ.

Devices Class: Class II

The Kirwan 41-34XX Series of Disposable Nerve Stimulating Probes are intended to be connected to a nerve monitoring unit, such as the Neurosign 100 Nerve Monitor, which requires a standard 1.5mm DIN 42802 touch proof connector, in order to provide an electrical path by which electrical impulses may pass from the monitoring unit to the patient, thus effecting nerve stimulation to assist its user in locating and identifying motor nerves.

The Disposable Nerve Stimulator Probes are surface electrodes used to stimulate nerves during various surgical procedures. They may be used on the surface of the skin, or on the surface of surgically exposed tissue, and as such, they are not intended nor designed to be inserted into tissue.

Technological safety and effectiveness is established by the fact that these probes do not contain any new technological risks or characteristics when compared to legally marketed devices offered here as predicates. Their design, materials and function were intended to be, and are virtually identical to the predicates. The

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Contact: Kevin P. Prario, Director of Regulatory Affairs
Date prepared: 8/19/2010

exceptions being the handle grip pattern and the probe insulation (where applicable), both were selected to enhance the design without compromising their substantial equivalence in regards to intended use, technological safety and effectiveness and performance. Testing to current dielectric strength and biocompatibility requirements assured that there was no compromise. Their energy source is of course identical. They are manufactured according to established standards with the technological characteristics of each probe listed on its labeling.

There are no applicable performance standards listed for these devices under Section 514 of the Food, drug and Cosmetic Act. Nonetheless, Kirwan 41-34XX Series of Disposable Nerve Stimulating Probes have been tested and manufactured in accordance with prevailing standards and guidelines in order to assure safety and efficacy. Kirwan Disposable Nerve Stimulating Probes have been found to comply with the requirements of the applicable sections within the following standards and guidelines;

- ISO 10993-1, Biological evaluation of medical devices – Part 1: Guidance on the selection of tests.
- IEC 60601-1, Medical electrical equipment.
- IEC 60601-2-10, medical electrical equipment, Part 2; particular requirements for the safety on nerve and muscle stimulators.
- ISO 11137 -1/2, Sterilization of health care products – requirements for validation and routine control-radiation sterilization.

Safety and hazard analysis has determined that the hazard conditions for the 41-34XX Series of Disposable Nerve Stimulating Probes range in the low-to-moderate level and for this reason are acceptable.

Therefore, the Kirwan 41-34XX Series of Disposable Nerve Stimulating Probes are substantially equivalent in intended use, technological safety and effectiveness and perform as well as the following predicates:

- Magstim 3600-00, 3601-00, 3602-00 and 3603-00 Disposable Probes, Manufactured by Technomed Europe, under 510(k), K050325.

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

Kirwan Surgical Products LLC
c/o Mr. Kevin P. Prario
Director of Regulatory Affairs
180 Enterprise Drive
Marshfield, MA 02050

AUG 19 2010

Re: K100912
Trade/Device Name: 41-34XX Series of Kirwan Disposable Nerve Stimulating Probes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: July 14, 2010
Received: July 15, 2010

Dear Mr. Prario:

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

K100912

Indications for Use

510(k) Number (if known): _____

Device Name:

Models: 41-34XX Series of Kirwan Disposable Nerve Stimulating Probes.

Indications for Use:

The Kirwan 41-34XX Series of Disposable Nerve Stimulating Probes are intended to be connected to a nerve monitoring unit, such as the Neurosign 100 Nerve Monitor, which requires a standard 1.5mm DIN 42802 touch proof connector, in order to provide an electrical path by which electrical impulses may pass from the monitoring unit to the patient, thus effecting nerve stimulation to assist its user in locating and identifying motor nerves.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100912

Prescription Use X
(Per 21 CFR 801.109)