K040639

ISurgical
26625 Countryside Lake Drive
Countryside Lake, IL 60060

MAY 21 2004

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12.0 510(k) SUMMARY

12.1 Summary Date: March 3, 2004

12.2 Company Name: ISurgical
26625 Countryside Lake Drive
Mundelein, IL 60060

12.3 Contact: Ken Leiser, Owner
12.4 Phone: 847-949-9744
12.5 Fax: 847-949-4934

12.6 Device Identification:

Proprietary Name:	ISurg Disposable Subdermal Needle Electrodes
Common Name:	Needle Electrodes
Classification Name:	Electrode, Needle (per 21 CFR section 882.1350)
Class:	Class II
Product Code:	GXZ

12.7 Predicate Devices:

510(k) Number:	K990015
Manufacturer:	Technomed Europe
Trade Name:	Technomed EEG/EMG Needle Electrodes
Product Code:	GXZ

510(k) Number:	K010019
Manufacturer:	Nicolet Biomedical, Incorporated
Trade Name:	Sterile Subdermal Needle Electrodes
Product Code:	GXZ

510(k) Number:	K022914
Manufacturer:	Rhythmlink International, LLC
Trade Name:	Rhythmlink International Subdermal Needle Electrodes
Product Code:	GXZ

12.8 Description:

ISurg Disposable Subdermal Needle Electrodes are the conduit between the monitoring equipment and a patient. The electrode has a small gauge stainless steel needle on one end (which is subdermally positioned by a licensed physician or technologist under his supervision) and a safety connector on the other (a safety connector which is connected to the monitoring equipment) with a small gauge wire connecting the two. The safety connector is an industry standard DIN 42802 protected connector and cannot be connected to an AC outlet.

ISurg Disposable Subdermal Needle Electrodes are used in the study of biopotentials such as electroencephalography (EEG), electromyography (EMG), nerve conduction and evoked potentials. They are "Rx Only", disposable (for "Single Use Only"), sterile and invasive as they are placed subcutaneously in or near nerve and muscle tissue.

12.9 Intended Use:

ISurg Disposable Subdermal Needle Electrodes are intended for use with monitoring, recording and stimulation equipment specifically designed for the recording of biopotential signals from electroencephalography (EEG), electromyography (EMG) and nerve potentials studies. ISurg Disposable Subdermal Needle Electrodes are "Rx Only", intended for "Single Use Only" and "Sterile".

12.10 Technological Characteristics:

The ISurg Disposable Subdermal Needle Electrode consists of an insulated wire with a small gauge stainless steel needle on one end, and a safety connector on the other that cannot be plugged into an AC power outlet.

The materials are substantially equivalent to those used in the predicate devices; however, ISurgical injection molds the needle-wire bond to insulate and provide a strong, tight seal around the needle and wire for strength and fluid occlusion. The DIN 42802 safety connector is molded to provide industry standard connectivity, insulate the terminal and provide wire stress relief by design.

12.11 Conclusions:

The ISurg Disposable Subdermal Needle Electrode is 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

MAY 21 2004

Mr. Ken Leiser
ISurgical
26625 Countryside Lake Drive
Countryside Lake, Illinois 60060

Re: K040639
Trade/Device Name: ISurg Disposable Subdermal Needle Electrodes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: II
Product Code: GXZ
Dated: March 8, 2004
Received: March 12, 2004

Dear Mr. Leiser:

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ISURGICAL PREMARKET NOTIFICATION

510(k) Number (if known) K040639

4.0 INDICATIONS FOR USE

Device Name: ISurg Disposable Subdermal Needle Electrodes

Indications For Use: ISurg Disposable Subdermal Needle Electrodes are intended for use with monitoring, recording and electrical stimulation equipment specifically designed for the recording of biopotential signals from electroencephagraphy (EEG), electromyography (EMG) and nerve potential studies. ISurg Disposable Subdermal Needle Electrodes are "Rx Only", intended for "Single Use Only" and "Sterile".

Prescription Use Only ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040639