K112426

APR - 2 2012

510(k) Summary (rev.02)
(per 21 CFR 807.92.(c))

1. Submitter's information

Company Name	Xi'an Friendship Medical Electronics Co., Ltd.
Company Address	No.9 Gao Xin 1st Road, High-Tech Development Zone, Xi'an, Shaanxi, 710075 P.R.China
Contact Person	Zhai Tao (Sales Department Manager)
Phone Numbers	86 29 88225200 Ext. 602
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Date Prepared	3/27/2012

2. Device Name

Trade name	Xian Friendship Disposable Nerve Stimulator Probes
Devices type	1. Disposable Monopolar Direct Nerve Stimulator Probe 2. Disposable Flush Tip Direct Nerve Stimulator Probe 3. Disposable Ball Tip Direct Nerve Stimulator Probe 4. Disposable Direct Concentric Nerve Stimulator Probe 5.Disposable Bipolar Direct Nerve Stimulator Probe 6.Disposable Hook Nerve Probe(Double Hook/ Triple Hook)
Common Name:	Surgical Nerve Stimulator/Locator
Classification Name:	Stimulator, Nerve (21. CFR 874.1820)
Product Code:	ETN,
Classification:	Class II (Performance Standards)
Panel:	Ear, Nose and Throat Devices

3. Predicate Device

Company	510(k) number	Device Name
Axon Systems, Inc.	K062996	Axon Systems Disposable Stimulator Probes
Medtronic Xomed, Inc.	K031003	Stimulus/Dissection Instruments, Ball-Tip Probes
Cadwell Laboratories, Inc.	K103128	Cadwell Disposable Stimulator Probes

4. Devices Description

Stimulator probes are used as the medium to deliver electrical stimulation to tissue during intraoperative neurological monitoring. The probes are available in three electrical

configurations such as monopolar, bipolar and concentric forms according to the required application. The probes are supplied sterile and are for single use only.

The probes are connected to an electrical stimulator using a flexible lead wire(s) and a "touch-proof' safety connector(s) on the distal end.

Stimulator probes are used by the surgeon to locate and identify motor nerves and spinal nerve roots and to assess nerve function. Bipolar probes may also be used to record nerve action potentials directly from the nerve.

The probes are designed with a plastic handle and stainless steel active electrode shaft insulated to the tip. The probe shaft may be bent to allow viewing access under a microscope.

Concentric Probes is designed with an outer anode pole and center cathode pole separated by insulation. Tip diameter approx 1mm.

Monopolar electrodes require a separate stimulator return electrode and the Monopolar probe is insulated to the tip with only a stimulating "ball" or "tip" exposed.

Bipolar probe has a fully insulated probe shaft with two 1 mm exposed flush tips. The anode and cathode tips can spread up to 3 mm apart and will penetrate tissue for stimulation current to flow.

5. Indications for Use

Xian Friendship Disposable Nerve Stimulator Probes is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

Xian Friendship Disposable Nerve Stimulator Probes are sterile (EtO), single-patient-use device.

6. Technological characteristics

Xian Friendship Disposable Nerve Stimulator Probes consist of an insulated probe shaft of various lengths mounted to plastic handle. The probe shaft is electrically connected to a DIN 42802"touch-proof' safety connector on the other end. The probe is supplied in a sterile pouch. Materials used are the same as in the predicate devices.

Xian Friendship Disposable Nerve Stimulator Probes are substantially equivalent to the predicate devices with regard to the design, construction, material, mechanical and electrical performance and application. More detail information on the Table 1.

Table 1 Product Comparison Table(1)

Features & Description	Predicate Device			Subject Device
Product name	Axon Systems Disposable Stimulator Probes	Stimulus/Dissection Instruments, Ball-Tip Probes	Cadwell Disposable StimulatorProbes	Xian Friendship Disposable Nerve Stimulator Probes
510(K) clearance numbers	K062996	K031003	K103128	--
Manufacture	Axon Systems, Inc.	Medtronic Xomed, Inc.	Cadwell Laboratories, Inc.	Xi'an Friendship Medical Electronics Co., Ltd.
Intend for use	To locate, identify and monitor cranial motor nerves, peripheral nerves and splnal nerve roots during surgery.	The Stimulus-Dissection Instruments are indicated for tissue dissection and stimulation of cranial and peripheral motor nerves for location and identification during surgery, including spinal nerve roots.	Cadwell Disposable Stimulator Probe is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery. The Cadwell Disposable Stimulator Probe is a single patient use device.	Xian Friendship Disposable Nerve Stimulator Probes is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery. Xian Friendship Disposable Nerve Stimulator Probes are sterile (EtO), single-patient-use device.
Configuration	Monopolar probe Bipolar probe Concentric probe			Monopolar probe Bipolar probe Concentric probe Tripolar probe

Table 1 Product Comparison Table(2)

Features & Description		Predicate Device	Subject Device
Shape of tip		standard tip, ball, Flush Tip	Standard tip, Ball, Flush Tip Hook
Connector		DIN 42802"touch-proof' safety	Same as"Predicate Device"
Material	Shaft	Stainless steel SST 304	Stainless steel SST 304
	Shaft Insulation	PTFE	PTFE
	Handle	Medical Grade ABS	Medical Grade ABS
	Lead Wire	Tin Plated Coppe	Tin Plated Coppe
	Lead Wire Insulation	Medical Grade PVC	Medical Grade PVC
Single Patient Use		Sterile-Single Patient Use	Sterile-Single Patient Use
Method of Sterilization		EtO	EtO
Packaging		1059B coating TYVEK layer+ PE/PET Medical film pouch	Same as "Predicate Device"
Shelf life		36 months	36 months

7. Summary of Performance Data

Bench testing for mechanical and electrical performance was conducted to verify that the device meets design specifications and performance characteristics in accordance with Xian Friendship Disposable Nerve Stimulator Probe's internal specifications. In addition, bench testing was also performed to demonstrate that the Xian Friendship Disposable Nerve Stimulator Probe is substantially equivalent to the predicate devices.

8. Safety & Effectiveness

Xian Friendship Disposable Nerve Stimulator 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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c/o Mr. Chu Xiaoan
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No. 209 Bei Si Hu Zhong Rd.
Haidian Dis
Beijing, 100083, P.R. China

APR - 2 2012

Re: K112426
Trade/Device Name: Xian Friendship Disposable Nerve Stimulator Probes
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: March 28, 2012
Received: March 28, 2012

Dear Mr. Chu Xiaoan:

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

K112426

Section 4.0 Indications for Use Statement

INDICATIONS FOR USE

Applicant: Xi'an Friendship Medical Electronics Co., Ltd.

510(k) Number (if known): * K112426

Device Name: Xian Friendship Disposable Nerve Stimulator Probes

Indications For Use:

Xian Friendship Disposable Nerve Stimulator Probes is used to perform localized stimulation of neural tissue and to locate, identify and monitor cranial motor nerves, peripheral nerves and spinal nerve roots during surgery.

Xian Friendship Disposable Nerve Stimulator Probes are sterile (EtO), single-patient-use device.

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

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K112426