K121743

MAR 2 8 2013

EasyMed Instruments Co., LTD.
5/F – 6/F, block A, Gupo Gongmao Building, Fengxin Road,
Fengxiang Industrial District, Daliang, Shunde, Foshan, CHINA 528300

Phone: +86 757 2809 1300

510(k) SUMMARY
21 CFR 807.92(c)

SUBMITTER INFORMATION

510k Owner:	EasyMed Instruments Co., LTD.
Company Address:	5/F – 6/F, block A, Gupo Gongmao Building, Fengxin Road, Fengxiang Industrial District, Daliang, Shunde, Foshan, CHINA 528300
Company Phone:	+86 757 2809 1300
Contact Person:	Wu Tingjie/ Owner
Date Summary Prepared:	April 17, 2012
Date of Updated Summary:	March 27, 2013

DEVICE INFORMATION

Trade/Proprietary Name:	EasyMed Instruments Co., LTD. Peripheral Nerve Stimulator
Common/Usual Names:	Peripheral Nerve Stimulator Battery-Powered Nerve Stimulator
Classification Name:	Electrical Peripheral Nerve Stimulator 21 CFR 868.2775
Product Code:	BXN

IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510k No.
Life-Tech Intl., Inc.	MiniStim	K913184

DEVICE DESCRIPTION

The EasyMed Peripheral Nerve Stimulator devices are battery powered peripheral nerve stimulators which provide low electrical direct current (DC) stimulation in order to determine the level of anesthetic nerve block. The Stimulus Amplitude control dial provides variable current control (0 to 70 mA into a 2K ohm load).

The Output Stimulus Pulse Indicator flashes each time current passes through the patient. Functions include: Train-of-Four, Twitch, and 100Hz Tetanus. The device offers sufficient output to ensure supramaximal stimulation: from 0 to 70 mA.

All finished products are tested and must meet all required release specifications before distribution. Testing includes physical testing (e.g. Pulse Amplitude, Pulse Width, Pulse Frequency and Low Battery Voltage Indicator) and visual examination.

INTENDED USE

EasyMed Instruments Co., LTD. Peripheral Nerve Stimulator is a battery-powered device intended for monitoring the magnitude of neuromuscular blocks in general anesthesia, by delivering an electrical stimuls near a peripheral motor nerve.

TECHNOLOGICAL CHARACTERISTICS

The technical characteristics of the EasyMed Peripheral Nerve Stimulators are similar to those of the predicate device in design, energy source, intended use and function. Like the predicate device, the EasyMed Peripheral Nerve Stimulators are devices used to apply an electric current to a patient to test the level of pharmacological effect of anesthetic drugs and gases. A comparative summary of the EasyMed device to the predicate device is provided in Section 12.0, Table 1.

PERFORMANCE DATA (e.g. non-clinical testing)

The EasyMed Peripheral Nerve Stimulator underwent the tests noted in the below table and results are indicated as well. The full test report can be found in Section 21.0 Appendix - Appendix VIII.

Test	Test Requirement	Test Method	Result
Electromagnetic Interference – Radiated Emission (30 MHz to 1 GHz)	EN 60601-1-2: 2007	EN 55011: 2009 + A1: 2010	Pass
Electromagnetic Susceptibility – ESD	EN 60601-1-2: 2007	EN 61000-4-2: 2009	Pass
Electromagnetic Susceptibility – Radiated Immunity (90 MHz to 2.5 GHz)	EN 60601-1-2: 2007	EN 61000-4-3: 2006 + A1: 2008 + A2: 2010	Pass
Electromagnetic Susceptibility – Power-frequency magnetic field immunity	EN 60601-1-2: 2007	EN 61000-4-8:1993 + A1: 2001	Pass

BASIS OF SUBSTANTIAL EQUIVALENCE/CONCLUSION

EasyMed Peripheral Nerve Stimulators have been tested and found to perform as intended. EasyMed Peripheral Nerve Stimulators have been compared to legally cleared predicate device and found to be substantially equivalent. Substantial equivalence testing results can be found in section 12.0.

The EasyMed Peripheral Nerve Stimulator and Stimulator Plus models have the same functions with the following exceptions: the Peripheral Nerve Stimulator functions do not include double burst and 2 tetanus options (50 Hz and 100 Hz).

STANDARDS

- ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
- EN 60601-1-2: 2007 (Second edition, 2001), Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 28, 2013

SunMed Limited Liability Company
C/O Mr. Wu Tingjie
EasyMed Instruments Company, Limited
5/F – 6/F, Block A, Gupo Gongmao Building
Fengxin Road, Fengxiang Industrial District
Daliang, Shunde, Foshan
China 528300

Re: K121743
Trade/Device Name: Peripheral Nerve Stimulator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: February 22, 2013
Received: February 25, 2013

Dear Mr. Tingjie:

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,

Kwame O. Ulmer -S

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121743

Device Name: Peripheral Nerve Stimulator

Indications for Use: The EasyMed InstrumentsCo., LTD. Peripheral Nerve Stimulator is a battery -powered device intended for monitoring the magnitude of neuromuscular blocks in general anesthesia, by delivering an electrical stimulus near a peripheral motor nerve.

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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)

Lester W. Schultheis Jr
2013.03.27 12:42:44 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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