DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 13, 2016

EasyMed Instrument Co., Ltd.
Jeffery Wu (Tingjie Wu)
General Manager
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Fengxin Road, Fengxiang Industrial District
Daliang, 528300
Shunde, Foshan, Guangdong, China

Re: K153045
Trade/Device Name: SunStim™ Peripheral Nerve Stimulator/SunStim™ Plus Peripheral Nerve Stimulator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: BXN
Dated: February 18, 2016
Received: April 08, 2016

Dear Jeffery Wu:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153045

Device Name
SunStim Peripheral Nerve Stimulator /
SunStim Plus Peripheral Nerve Stimulator

Indications for Use *(Describe)*
SunStim Peripheral Nerve Stimulator and SunStim Plus Peripheral Nerve Stimulator are a battery-powered device intended for monitoring the magnitude of neuromuscular block in general anesthesia, by delivering an electrical stimulus near a peripheral motor nerve.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6.0

510(k) Summary

510(k) Summary

Date of submission prepared: 12 May 2016

Submitter:	EasyMed Instruments Co., Ltd.
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Tel:	+86 757 2809 1300
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Official Contact:	Jeffery Wu (Wu Tingjie)
E-Mail:	jeffery@easymed.com.cn

Address of the manufacturing facility: The same as above

SUBMITTED DEVICE:

Proprietary or Trade Name:	SunStim™ Peripheral Nerve Stimulator / SunStim™ Plus Peripheral Nerve Stimulator
Common/Usual Name:	Peripheral Nerve Stimulator Battery-Powered Nerve Stimulator
Classification Name:	Electrical Peripheral Nerve Stimulator 21 CFR 868.2775
Product Code:	BXN
Device Panel:	Anesthesiology
Device Classification:	Class II
Prior submission:	No

PREDICATE DEVICE:

Device Name:	EasyMed Instruments Co., LTD. Peripheral Nerve Stimulator
Manufacturer:	EasyMed Instruments Co., Ltd.
510(k) Number:	K121743
Product Code:	BXN
Trade name:	Microstim Peripheral Nerve Stimulator

INTENDED USE:

SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator are a battery-powered device intended for monitoring the magnitude of neuromuscular block in general anesthesia, by delivering an electrical stimulus near a peripheral motor nerve.

DEVICE DESCRIPTION:

SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator 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: Double Burst (DBS), Train-of-Four, Twitch, and 100Hz Tetanus. The device offers sufficient output to ensure supramaximal stimulation: from 0 to 70 mA. SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator models have the same functions with the following exceptions: the SunStim™ Peripheral Nerve Stimulator functions do not include Double Burst and the 50 Hz Tetanus option.

TECHNOLOGICAL CHARACTERISTICS

The technical characteristics of the modified Peripheral Nerve Stimulators (i.e. SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator) are the same as those of the original legally marketed Peripheral Nerve Stimulators (K121743) in energy source, intended use and functions. Like the predicate device, SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator are devices used to apply an electric current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

The devices, both the predicated ones and modified ones, can be divided into two parts:

1. The timing control
This part can be considered to be simplified as a switch controlling the device high voltage output on or off.
In our original design this part uses a simple logical circuit; in our modified design this part uses a simple 8 bits MCU (Micro Control Unit) so that the circuitry can be simplified.

2. The voltage generator
This part generates voltage to the setting level, and output the stimulating signal at the time when the output of timing control part is set to on.

This part is not changed in this modification.

The design principle and operational principle of the modified Peripheral Nerve Stimulators (i.e.

SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator) are the same as those of original legally marketed Peripheral Nerve Stimulators (K121743). The difference is an MCU is used inside the modified Peripheral Nerve Stimulators to take the place of timing control part of the predicate device.

This modification does not affect the device's intended use or alter the device's fundamental scientific technology.

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

The SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator underwent the tests and recognized consensus standards noted in the below table.

FDA recognition No.	Standard Title
19-5	AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod). (General I (QS/RM))
19-2	AAMI / ANSI / IEC 60601-1-2:2007/(R) 2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3). (General II (ES/EMC))
5-40	ISO 14971: Second Edition 2007-03-01 Medical devices- Application of Risk Management To Medical Devices. (General I (QS/RM))
13-8	IEC 62304 First Edition 2006-05, Medical devices software- Software life cycle processes (Software/ Informatics)

Test results show that the modification for the new device do not affect the safety and effectiveness.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The modified Peripheral Nerve Stimulators (i.e. SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator) are of the following similarities to the original legally marketed Peripheral Nerve Stimulators (K121743)

- The same intended use;
- Use the same operating principle;

- Incorporate the same basic design principle;
- The same operating modes;
- The same stimulation parameters

The modified Peripheral Nerve Stimulators (i.e. SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator) have the same intended use and similar technological characteristics to the original legally marketed Peripheral Nerve Stimulators (K121743). Thus, the modified Peripheral Nerve Stimulators (i.e. SunStim™ Peripheral Nerve Stimulator and SunStim™ Plus Peripheral Nerve Stimulator) are substantially equivalent to the predicate device.

The modifications do not affect the device's intended use or alter the device's fundamental scientific technology. The modified devices are as safe, as effective and are substantially equivalent to the predicated device.