DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 5, 2016

Halyard Health - Irvine
Maria Pronina
Technical Leader, Regulatory Affairs
43 Discovery, Suite 100
Irvine, California 92618

Re: K162048
Trade/Device Name: EZstim* III Peripheral Nerve Stimulator/Nerve Locator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: KOI
Dated: November 1, 2016
Received: November 2, 2016

Dear Maria Pronina:

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,

Tejashri Purohit-Sheth, M.D.

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

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K162048

Device Name
EZstim*III Peripheral Nerve Stimulator/Nerve Locator

Indications for Use *(Describe)*
The EZstim*III is a battery powered Peripheral Nerve Stimulator/Nerve Locator with two (2) indications for use:

(1) on the high (0.05 - 80 mA) output current range, the device is used to monitor the effects of skeletal muscle relaxants during general anesthesia.

(2) on the low (0.05-5.0 mA) output current range, it is used as a Nerve Locator to help locate the tip of a hypodermic needle near the nerve to which local anesthesia is to be delivered in Regional Nerve Block procedures.

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.

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510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92

The assigned 510(k) number is:

Submitted by:	Halyard Health 43 Discovery, Suite 100 Irvine, CA 92618
Establishment Registration Number:	2026095
Contact Person:	Maria Pronina Technical Leader, Regulatory Affairs Phone: 949.923.2325 Fax: 678.389.9791 e-mail: maria.pronina@hyh.com
Date Summary Prepared:	December 5, 2016
Reason for Premarket Notification:	New Device
Trade Name:	EZstim* III Peripheral Nerve Stimulator/Nerve Locator
Common/Usual Name:	Stimulator, Nerve, Peripheral, Electric
Regulation Name:	Electrical peripheral nerve stimulator
Classification Regulation:	21 CFR 868.2775
Product Code:	KOI
Regulatory Class:	Class II
Panel:	73 - Anesthesiology
Predicate Device:	Life-Tech, Inc. received clearance for the Electrical Peripheral Nerve Stimulator, EZstim ES100 (K954505). Ownership of K954505 was transferred to Halyard Health (formerly Kimberly-Clark Healthcare) in 2013.

5.1 Description of the Device

The EZstim* III (Model ES500) is both a constant current Peripheral Nerve Stimulator (HIGH output current range) and a Peripheral Nerve Locator (LOW output current range). Output current range is determined by the model of patient lead cable connected to the unit.

- When the Halyard NSL-5 patient lead cable is connected, the unit automatically sets to the HIGH output current range (0.05 to 80 mA), with no stimulus mode selected (null mode). When the user selects a stimulus mode (i.e., 1 or 2 Hz Twitch, 50 Hz Tetanus, 100 Hz Tetanus, Double-Burst, or Train-of-Four), the unit functions as a nerve stimulator for use in monitoring the effects of skeletal muscle relaxants on the neuromuscular junction.

- When the Halyard RBW-5U patient lead cable is connected, the unit automatically sets to the LOW output current range (0.05 to 5.0 mA). In this range, the unit functions as a nerve locator for use in regional nerve block procedures.

5.2 Indications for Use

EZstim* III Peripheral Nerve Stimulator/Nerve Locator is a battery powered Peripheral Nerve Stimulator / Nerve Locator with two (2) indications for use:

(1) on the high (0.05 – 80 mA) output current range, the device is used to monitor the effects of skeletal muscle relaxants during general anesthesia.

(2) on the low (0.05 – 5.0 mA) output current range, it is used as a Nerve Locator to help locate the tip of a hypodermic needle near the nerve to which local anesthesia is to be delivered in Regional Nerve Block procedures.

5.3 Summary of Substantial Equivalence:

The intended use, materials, performance, and technological principles of operation of the EZstim* III Peripheral Nerve Stimulator/Nerve Locator (Model ES500) are substantially equivalent to the predicate device, EZstim (Model ES100) cleared under K954505. Just as with the predicate, energy is delivered to the patient via lead cable accessories that connect to the ES500 output connectors. As with the predicate device, stimulus control functions on the ES500 allow control of the output current amplitude and electrical pulse pattern to deliver the appropriate stimulus for a given application.

The following summary table compares the technological characteristics of the subject EZstim* III (Model ES500) to the predicate EZstim (Model ES100) device.

Characteristic	**Predicate Device** **EZstim (ES100)** **(K954505)**	**Subject Device** **EZstim* III (ES500)** **(K162048)**

Characteristic	Predicate Device EZstim (ES100) (K954505)	Subject Device EZstim* III (ES500) (K162048)
Regulation Product Code	KOI	**SAME**
Manufacturer	Currently Halyard Health	**SAME**
Indications for Use	The EZstim has two indications for use: (1) On the high (0-80mA) current range the device is used to monitor the effects of skeletal muscle relaxants during general anesthesia. (2) On the low (0-8mA) it is used as a nerve locator in Regional Nerve Block procedures.	The EZstim* III has two (2) indications for use: (1) On the high (0.05 – 80mA) output current range, the device is used to monitor the effects of skeletal muscle relaxants during general anesthesia. (2) On the low (0.05 – 5.0mA) output current range, it is used as a nerve Locator to help locate the tip of a hypodermic needle near the nerve to which local anesthesia is to be delivered in Regional Nerve Block procedures.
Physical Configuration	Hand-Held	**SAME**
Size	3.7” (9.4cm) W x 6.2” (15.8cm) L x 1.4” (3.6cm) H	3.5” (8.5 cm) W x 6.5” (16.3 cm) L x 2” (5 cm) H (including knob)
Weight	11.5 oz (326 g)	9.6 oz (275gm)
Output Current	HIGH Range: 0 to 80 mA ± 2 mA. LOW Range: 0.0 to 8.0 mA ± 0.2mA.	High Range: adjustable high current mode regulated output 0.05 to 80 mA ± 5% into 3.74 k ohms or less Low Range: adjustable current regulated 0.05 to 5.0 mA ± 1% into 11.5 k ohms or less
Stimulation Categories	Double Burst, Train-of-Four, Twitch, or Tetanus	**SAME**
Display	Single-line alphanumeric LCD with 16 characters	High contrast LCD approximately 1.0” high x 2.45” wide
Mounting Bracket	Mounting Bracket to an IV pole is available as an optional accessory.	**SAME**
Expected Service Life	5 Years	**SAME**
Performance Testing Data	• EMC Compatibility per “FDA Reviewers Guidance for Pre-market Notification Submission for the anesthesiology and respiratory device branch.” (Based on IEC 801.) • Software Verification and Validation Testing per FDA Guidance for software with Minor Level of Concern • Hardware mechanical and functional Testing • Packaging - None	• IEC 60601-1 (3.1 edition) standard for safety and the IEC 60601-1-2 (4th edition) standard for EMC. • Software Verification and Validation Testing per FDA Guidance for software with Moderate Level of Concern (IEC 62304 Class B). • Hardware mechanical and functional Testing • Packaging verification simulation testing
Biocompatibility	Not Applicable (device is non-patient contacting)	**SAME**
Power Source	One 9 Volt Alkaline Battery	**SAME**
Sterilization	Non-Sterile	**SAME**

The Indications for Use statements of the subject and predicate devices are similar and both are intended for 1) monitoring effects of skeletal muscle relaxants during general anesthesia, and 2) use as a nerve locator in Regional Nerve Block procedures. The only differences in the Indications for Use statements of the two devices are the referenced current ranges specified (i.e., The predicate device High Current Range is 0 to 80 mA, while the subject device High Current Range is 0.05 to 80 mA. The predicate device Low Current Range is 0 to 8.0 mA, while the subject device Low current range is 0.05 to 5.0 mA.) The lower limit for both the High and Low Current Ranges was changed to 0.05 mA to allow quantitative verification of this lower limit value because it's not possible to verify 0mA. The upper limit of the Low Current Range was reduced to 5.0 mA to limit nerve exposure to higher current.

Neither of these differences to details within the Indications for Use statement impact the intended use or function of the device; and do not raise different questions of safety or effectiveness of the device when used as labeled.

5.4 Summary of Non-Clinical Testing

The following testing of the EZstim* III Peripheral Nerve Stimulator/Nerve Locator was performed in accordance with the requirements of the design control guidelines and established quality assurance processes to demonstrate substantial equivalence of the subject device to the predicate device.

Test Name and Description	Pass/Fail
IEC 60601 Safety Testing Electrostatic Discharge Radiated Immunity, Conducted RD Immunity, Magnetic Field Immunity Description: Electrical Safety and Electromagnetic Compatibility (EMC) were tested and found to comply with IEC 60601-1 (3.1 Edition) standard and the IEC 60601-1.2 (4th Edition) standard for EMC: o Radiated Emissions o Electrostatic Discharge Immunity o Radiated RF Electromagnetic Fields Immunity o Immunity to proximity field from RF wireless communication equipment o Conducted Disturbances, Induced by RF Fields Immunity o Power Frequency Magnetic Fields Immunity o Leakage Current o Dielectric Voltage Withstand o Excessive Temperature o Humidity Preconditioning o Abnormal Operation and Fault Conditions	Pass
Software Verification	Pass

Description: The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software validation tests demonstrated that the software version meets the design requirements.	
Hardware Verification Description: Hardware Verification test was conducted to ensure that the ES500 Hardware and Software system functions as intended and included the following: o Output current test o Beeper test o Battery removal test o Weight test o Internal temperature test The Hardware Verification test demonstrates that the design outputs meet the design input	Pass
Packaging Verification Description: Packaging distribution simulation testing was conducted per ASTM D4169-14 (Standard Practice for Performance Testing of Shipping Containers and Systems). The ES500 went through the following distribution simulation: o Temperature and Humidity Conditioning o Schedule A – Manual Handling (First Drop Sequence) o Schedule C – Vehicle Stacking o Schedule F – Loose Load Vibration o Schedule E – Vehicle Vibration o Schedule J – Concentrated Impact o Schedule A – Manual Handling (Second Drop Sequence)	Pass
Electrosurgery Test Description: Electrosurgery Immunity testing was successfully completed to ensure the ES500 device is electrosurgery compatible, where the device operates as intended in High Output Current mode. The electrosurgery immunity test demonstrated that the design output meets the design input requirements.	Pass
Battery Life Test Description:	Pass

Battery Life Test was conducted to ensure the duration of single 9V battery to function in accordance with the established acceptance criteria for the ES500 device. The battery life tests demonstrated that the design output meets the design input requirement.	
Battery Door Seal Integrity (Adhesive) Test Description: The Battery Door Seal Integrity (Adhesive) Test was conducted to ensure the adhesive gasket in the battery door compartment maintains integrity after battery replacements. The battery adhesive test demonstrated that the design output meets the design input requirement.	Pass

5.5 Summary of Clinical Testing

No clinical testing was required or performed since substantial equivalence of the device was supported by the non-clinical testing.

Conclusion

Based on the design and results of testing, the proposed new EZstim* III Peripheral Nerve Stimulator/Nerve Locator (Model ES500) device is as safe, as effective, and performs as well as or better than the predicate. The ES500 is substantially equivalent to the predicate (Model ES100).