DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 24, 2015

Halyard Health, Inc. (Formerly Kimberly-Clark Healthcare)
Lindsey Hedlund, MBA
Regulatory Affairs Coordinator
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K143095
Trade/Device Name: Ministim* Peripheral Nerve Stimulator Model MS-IVB
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: Class II
Product Code: BXN
Dated: December 19, 2014
Received: December 24, 2014

Dear Ms. Hedlund,

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 Keith
Director
Division of Anesthesiology,
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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)*
K143095

Device Name
MiniStim Peripheral Nerve Stimulator - Model MS-IVB

Indications for Use *(Describe)*
The Ministim MS-IVB is a battery-powered peripheral nerve stimulator for monitoring the effects of skeletal muscle relaxants.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Section 8.0 – 510(k) Summary

The 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared	March 20, 2015
Applicant	Halyard Health (formerly Kimberly-Clark Health Care) 5405 Windward Parkway Alpharetta, GA 30004
Official Correspondent	Lindsey Hedlund, MBA Regulatory Affairs Coordinator Tel: 470-448-5441 Fax: 920.225.4932 Email: lindsey.hedlund@hyh.com
Trade Name	MiniStim* Peripheral Nerve Stimulator – Model MS-IVB
Classification Name	Stimulator, nerve, battery-powered
Device Classification and Product Code	Class II per 21 CFR §868.2775 Product Code - BXN
Predicate Devices	The MS-III MiniStim* Peripheral Nerve Stimulator was cleared by K913184, under the Life-Tech, Inc. applicant. Ownership of the 510(k) was transferred to Kimberly-Clark in 2013.

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Section 8.0 – 510(k) Summary, Continued

Device Description

The MS-IVB is a nerve stimulator with selectable stimulus output waveforms and adjustable output amplitude. The stimulus output is intended for monitoring the depth of patient muscle and nerve relaxation while administering paralytic drugs for sedation anesthesia.

Characteristic	MS-IVB
Power Source	9V Alkaline Battery
Display	LED
Stimulus Modes	Twitch, Tetanus (50Hz and 100Hz), Train of Four, and Double Burst
Dimensions	2.4" W x 4.2" L x 1" H
Weight with Battery	6 oz
Current Output	Measured with load of 2K Ω± 10% • 0 to 50mA at 9.2 V • 0 to 42mA at 7.5 V (Low Battery Alert Threshold)

Indications for Use

The MiniStim* MS-IVB is a battery powered Peripheral Nerve Stimulator for monitoring the effects of skeletal muscle relaxants.

Technological Characteristics

The technical characteristics of the MiniStim* Peripheral Nerve Stimulator are similar to those of the predicate and currently marketed devices in design, energy source, intended use, and function. Unlike the predicate, the MS-IVB will have shut off time limits set on the Twitch and Tetanus pulse durations, as well as an idle time maximum. A comparative summary of the MiniStim* to the predicate device is provided in the following tables:

Continued on next page

Section 8.0 – 510(k) Summary, Continued

Comparison of the general features of the predicate, currently marketed, and subject devices

	MS-III (K913184)	**MS-IVB (Subject Device)**
FDA Classification	Class II (Regulation No. 868.2775)	**NO CHANGE**
FDA Product Code	BXN	**NO CHANGE**
Common Name	Peripheral Nerve Stimulator	**NO CHANGE**
Device Trade Name	MiniStim MS-III	MiniStim MS-IVB
Indications for Use	Peripheral nerve stimulators are used by the anesthesiologist or nurse anesthetist during surgery to monitor the effectiveness of muscle-relaxant drugs used in conjunction with general anesthesia to reduce the overall anesthesia level. In essence, the anesthesiologist observes the muscle twitch generated by the stimulator to determine when the twitch amplitude has declined by an amount which indicates effective action of the muscle relaxant drug.	The MiniStim* MS-IVB is a battery powered Peripheral Nerve Stimulator for monitoring the effects of skeletal muscle relaxants.
Physical Configuration	Handheld	**NO CHANGE**
User Feedback	LED	**NO CHANGE**
User Input	Membrane Switch and Dial	**NO CHANGE**
Power Source	9V Alkaline	**NO CHANGE**
Bovie Immunity	Not Tested	Immune
Level of Concern	Moderate	**NO CHANGE**

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Section 8.0 – 510(k) Summary, Continued

Comparison of the physical dimensions/specifications of the predicate, currently marketed, and subject devices

	MS-III (K913184)	**MS-IVB (Subject Device)**
Pulse Amplitude Control	Hardware	**NO CHANGE**
Pulse timing control	Times IC (Integrated Circuit)	**NO CHANGE**
Software Version	N/A – Analog	01.02.02.00
Sterilization Requirements	Not Sterile	**NO CHANGE**
Battery	9V alkaline battery	**NO CHANGE**
Size	2.4" W X 4.2"L x 0.8"	2.4" W X 4.2"L x 1"
Weight	5oz including battery	6oz including battery
Min Output Voltage	0V	**NO CHANGE**
Max Output Voltage	450 V± 10% (open circuit)	320V ± 10% (open circuit)
Output Current • **@ 9.2 V** • **@ 7.5 V** (Low Battery Alert Threshold)	Measured with load of 2K Ω± 10% • 0 to 50mA at 9.2 V • 0 to 42mA at 7.5 V (Low Battery Alert Threshold)	**NO CHANGE**
Conductive Shielding	Present	**Removed**
Processor	N/A	Texas Instruments MSP430G2553IPW20

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Section 8.0 – 510(k) Summary, Continued

Comparison of the functionalities of the predicate, currently marketed, and subject devices

	MS-III (K913184)	MS-IVB (Subject Device)
Pulse Width	0.22 milliseconds	**NO CHANGE**
Pulse Rise Time	<10μs open circuit	**NO CHANGE**
Train of Four	The Train of Four consists of two pulses per second for two seconds. The sequence is automatically repeated every 10 seconds.	**NO CHANGE** No change to the pattern. The automatic repeat of the pattern was removed based on user feedback.
Double Burst	Each Double Burst stimulus consists of 2 groups of 3 pulses each. The sequence is automatically repeated every 10 seconds. Within a group, the individual pulses are separated by 20ms (50Hz rate). The second group of three pulses follows the first after 750ms.	**NO CHANGE** No change to the pattern. The automatic repeat of the pattern was removed based on user feedback.
Tetanus Pulse Frequency	Each Tetanus Pulse consists of the optional 50 or 100 pulses per second while the button is held.	The Tetanus feature remains the same, however an additional feature of 30 second time limit was included to both the 50Hz and the 100HZ option to limit the pulse delivery duration.
Twitch Pulse Frequency	Each Twitch Pulse is one pulse per second. It is automatically repeated every second.	The Twitch Pulse frequency remains the same, however an additional feature of a 20 minute time limit was included for the pulse delivery duration.
Power On/Off	Press the button to turn unit ON or OFF. Indicator lights when the unit is ON and flashes when the battery is ready to be replaced.	The Power On/Off remains the same, however, an additional feature of an automatic shut off after 20 minutes of idle time was included.

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Section 8.0 – 510(k) Summary, Continued

Summary of Non-Clinical Testing

The MiniStim* Peripheral Nerve Stimulator – Model MS-IVB underwent the tests noted in the below table and results are indicated as well.

Test Name and Description	Pass/Fail
IEC 60601 Safety Testing Electrostatic Discharge, Radiated Immunity, Conducted RD Immunity, Magnetic Field Immunity	Pass
Software Verification	Pass
User Interface / Functionality	Pass
Waveform	Pass
Packaging and Labeling Verification	Pass

Summary of Clinical Testing

There was no clinical testing required to support the medical device as the Indications for Use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

Conclusion

Based on the intended use, technological characteristics, performance data, and nonclinical test, the subject MiniStim* Peripheral Nerve Stimulator, Model MS-IVB, is substantially equivalent and is as safe and as effective as the legally marketed predicate device K913184.