DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2016

HB Medical, Inc.
% Robyn Scopis
CEO
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, California 92831

Re: K160255
Trade/Device Name: HBOTC Muscle And Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: August 15, 2016
Received: August 16, 2016

Dear Robyn Scopis:

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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K160255

Device Name
HBOTC Muscle and Nerve Stimulator

Indications for Use *(Describe)*

Transcutaneous Electrical Nerve Stimulation:

1. For symptomatic relief and management of chronic pain
2. For adjunctive treatment in the management of post-surgical and post-traumatic pain
3. For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise and normal household and work activities

Powered Muscle Stimulator

1. To temporarily increase local blood circulation in healthy muscles
2. For muscle conditioning by stimulating healthy muscle in order to improve or facilitate muscle performance

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
K160255

510(k) Owner	HB Medical 5702 Bolsa Ave. Huntington Beach, CA 92649 Phone: (714) 330-7333 Facsimile: (714) 500-4092
Contact person	Robyn Scopis Regulatory Specialists, Inc. 1801 Edgecliff Drive Fullerton, CA 92831 Phone: 949.262.0411 Fax: 949.552.2821 Email: robyn@regulatoryspecialists.com

Preparation Date	September 13, 2016

Primary Product Code: NUH

Common Name	Transcutaneous electrical nerve stimulator for pain relief
Trade Name	HBOTC Muscle and Nerve Stimulator
Classification Name	stimulator, nerve, transcutaneous, over-the-counter
Regulation	882.5890
Class	Class II
Panel	Neurology

Secondary Product Code: NGX

Common Name	Powered muscle stimulator
Trade Name	HBOTC Muscle and Nerve Stimulator
Classification Name	stimulator, muscle, powered, for muscle conditioning
Regulation	890.5850
Class	Class II
Panel	Physical Medicine

Primary Predicate	K131910
Secondary Predicate	K112485
Third Predicate	K103738
Fourth Predicate	K102051

Description

The HBOTC is an OTC electrical nerve and muscle stimulator indicated for symptomatic relief and management of chronic pain as well as muscle conditioning and increasing local blood flow. The HBOTC consists of a portable battery-operated electrical stimulation device with two channels, two sets of lead wires, six packages of self-adhesive electrodes, and a battery charger. Each channel has a pair of buttons for selecting the desired frequency and a dial to control the intensity of the signal. The stimulator is also supplied with an output jack for each channel, a charging jack, timer buttons, and an LCD display.

Intended Use

The HBOTC is intended for use as a nerve and muscle stimulator for patients wanting symptomatic relief and management of chronic pain as well as muscle conditioning and increasing local blood flow.

Indications for Use

Transcutaneous Electrical Nerve Stimulation:

1. For symptomatic relief and management of chronic pain
2. For adjunctive treatment in the management of post-surgical and post-traumatic pain
3. For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise and normal household and work activities

Powered Muscle Stimulator

1. To temporarily increase local blood circulation in healthy muscles
2. For muscle conditioning by stimulating healthy muscle in order to improve or facilitate muscle performance

Comparison of Technological Characteristics to Predicate Devices

The predicates and the HBOTC were compared in the following areas and found to have minor different technological characteristics. The following differences have been determined to not impact the safety and effectiveness of the HBOTC:

510(k) Number	Subject Device HBOTC K160255	Primary Predicate MPP K131910	Secondary Predicate H4 K112485	Third Predicate H4 K103738	Fourth Predicate Pain Buddy K102051
Power Source	Ni-MH rechargeable battery (7.2 V)	Ni-MH rechargeable battery (7.2 V)	Ni-MH rechargeable battery (7.2 V)	Ni-MH rechargeable battery (7.2 V)	Two 1.5-Volt AAA disposable cells (3 V)
Intended Use	Transcutaneous Electrical Nerve Stimulation: 1. For symptomatic relief and management of chronic pain 2. For adjunctive treatment in the management of post-surgical and post-traumatic pain 3. For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise and normal household and	The MPP is to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise and normal household and work activities. The MPP is intended for muscle conditioning by stimulating muscle in order to improve or facilitate muscle performance.	The H-Wave H4 is indicated for the treatment of chronic pain, acute pain, post-surgical pain, and temporary pain.	1. Relaxation of muscle spasms; 2. Prevention or retardation of disuse atrophy; 3. Increasing local blood circulation; 4. Muscle re-education; 5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; 6. Maintaining or increasing range of motion.	TENS stimulation is used for symptomatic relief and management of chronic pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic pain.

	work activities Powered Muscle Stimulator 1. To temporarily increase local blood circulation in healthy muscles 2. For muscle conditioning by stimulating healthy muscle in order to improve or facilitate muscle performance				
Line Current Isolation	Yes (battery operated)	Yes (battery operated)	Yes (battery operated)	Yes (battery operated)	Yes (battery operated)
Patient Leakage Current					
Normal Condition	0	0	0	0	0
Single fault condition	0	0	0	0	0
Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0	0	0	0
Number of output modes	1	1	1	1	1
Number of output channels	2	2	2	2	1
synchronous or alternating	alternating	alternating	alternating	alternating	alternating
Method of Channel Isolation	galvanic	galvanic	galvanic	galvanic	galvanic

Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage
Software/firmware/microprocessor	Yes	Yes	Yes	Yes	Yes
Automatic Overload Trip	No	No	No	No	No
Automatic No-Load Trip	Yes	Yes	Yes	Yes	Yes
Automatic Shut Off?	No	No	No	No	No
Patient Override Control	Yes	Yes	Yes	Yes	Yes
Indicator Display					
On/ Off Status	Yes	Yes	Yes	Yes	Yes
Low Battery	Yes	Yes	Yes	Yes	Yes
Voltage/ Current Level	Yes	Yes	Yes	Yes	Yes
Weight	1.6 lb	1.6 lb	1.6 lb	1.6 lb	1.9 oz
Dimensions	7" x 4.5" x 1.5"	7" x 4.5" x 1.5"	7" x 4.5" x 1.5"	7" x 4.5" x 1.5"	4.9" x 1.4" x 0.6"
Housing materials and constructions	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws	ABS plastic housing fastened with screws
Waveform	biphasic	biphasic	biphasic	biphasic	biphasic
Frequency	1–70 Hz	1–70 Hz	1–70 Hz	1–70 Hz	8-80 Hz
Beat Frequency	N/A	N/A	N/A	N/A	N/A
Shape	spike with exponential decay	spike with exponential decay	spike with exponential decay	spike with exponential decay	Asymmetrical Bi-Phasic Rectangular
Maximum Output Voltage @500Ω	21v	21v	21v	21v	29v
Maximum Output Voltage @2kΩ	56v	56v	56v	56v	34v

Maximum Output Voltage @10kΩ	100v	100v	100v	100v	36v
Maximum Output Current @500Ω	42 mA	42 mA	42 mA	42 mA	60 mA
Maximum Output Current @2kΩ	28 mA	28 mA	28 mA	28 mA	17mA
Maximum Output Current @10kΩ	10 mA	10 mA	10 mA	10 mA	4mA
Pulse Width	5 ms @ 1 k ohms	5 ms @ 1 k ohms	5 ms @ 1 k ohms	5 ms @ 1 k ohms	160 µs
Net Charge	0 (equal positive and negative pulses)	0 (equal positive and negative pulses)	0 (equal positive and negative pulses)	0 (equal positive and negative pulses)	unknown
Maximum Phase Charge @500Ω	16.8 µC	16.8 µC	16.8 µC	16.8 µC	unknown
Maximum Current Density @500Ω	2 mA/cm²	2 mA/cm²	2 mA/cm²	2 mA/cm²	unknown
Maximum Power Density @500Ω	0.042 W/cm²	0.042 W/cm²	0.042 W/cm²	0.042 W/cm²	unknown
Burst Mode Pulses per burst	N/A	N/A	N/A	N/A	unknown
Burst Mode Bursts per second	N/A	N/A	N/A	N/A	unknown
ON Time (seconds)	N/A	N/A	N/A	N/A	unknown
OFF Time (seconds)	N/A	N/A	N/A	N/A	unknown

The following non-clinical performance tests were conducted:

Software Validation

IEC 60601-1 (2012): Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-11 (2015): Medical electrical equipment – Part 1-11: General Requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-2-10 (2012)/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the HBOTC is substantially equivalent to the predicates as a powered muscle stimulator and transcutaneous electrical nerve stimulator for pain relief.