October 17, 2018

Shenzhen Kentro Medical Electronics Co., Ltd
% Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg.1, Southward Ruifeng Business Center,
Guimiao Road
Shenzhen, Cn 518000 Guangdong

Re: K181728
Trade/Device Name: Muscle Trainer
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 14, 2018
Received: July 17, 2018

Dear Rain Yip:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181728

Device Name
Muscle Trainer

Indications for Use *(Describe)*
To be used to stimulate healthy muscles in order to improve and 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

Date: 2018-06-04

I. Submitter

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II. Device

Type of 510(k): Traditional
Common Name: Powered muscle stimulator
Trade Name: Muscle Trainer
Models: KTR-230 series, KTR-231, KTR-232, KTR-233, KTR-234
Classification Name: Stimulator, Muscle, Powered, For muscle conditioning
Review Panel: Physical Medicine
Regulatory Class: II
Product Code: NGX
Regulation Number: 21 CFR 890.5850

III. Predicate Device

Applicant	Predicate Device	510(k) Number	Approval Date
Well Brain International Ltd.	(Primary): GYMFORM®ABS & CORE/VDPGYCSET0042	K142055	May 11, 2015
HIVOX BIOTEK INC.	HIVOX OTC Electrical Stimulator/SEM44	K171803	Nov.29, 2017

IV. Device Description

Muscle Trainer is a product that adopts modern electronic science and technology to delivers electric pulses generated to the user's skin through the electrodes.

Muscle Trainer is mainly composed of the host and electrode patches, as well as it is powered by CR2023 battery. Of which, the electrode patch is cleared in K171381.

Muscle Trainer includes KTR-230 series (KTR-230B, KTR-230W, KTR-230P), KTR-231, KTR-232, KTR-233 and KTR-234 model. All models have three operation modes and one channel, which can give certain electrical pulse through electrode patches on the skin. Their technical parameters are slightly different, but they share the basically same characteristics:

- Electric pulse combination, 0~12 levels can be adjusted and chosen according to personal preference.
- CR2032 Button batteries (DC3V) power supply, easy to use and safe.

The main differences among them are the followings but not affect its intended use:

- Appearance
- The number of control button: KTR-230 series, KTR-231 and KTR-232 have two buttons to control; KTR-233 and KTR-234 have three buttons to control.
- The number of electrode patch used: KTR-230 series, KTR-233 and KTR-234 are equipped with one electrode patch; KTR-231 is equipped with six electrode patches as well as KTR-232 is equipped with two electrode patches.
- Applied parts: KTR-230 series, KTR-233 and KTR-234 apply to abdomen, shoulder, arm, thigh and calf; KTR-231 applies to abdomen in the place where between ribs and hip bones; KTR-232 applies to waist, shoulder, arm, thigh and calf.

V. Indications for Use

To be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

VI. Comparison of Technological Characteristics With the Predicate Devices

The Muscle Trainer is substantially equivalent to the predicated device based on intended use, design, specifications and performance.
The Muscle Trainer does not raise different questions of safety and effectiveness as compared to the predicate devices.
Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicate is provided below:

Comparison Elements	**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
510(k) number	K181728	K142055	K171803	/
Trade name	Muscle Trainer/KTR-230series, KTR-231, KTR-232, KTR-233, KTR-234	GYMFORM® ABS&CORE/ VDPGYCSET0042	HIVOX OTC Electrical Stimulator/SEM44	/
Product code	NGX	NGX	NUH NGX	/
Indication for use/Intended use	To be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	GYMFORM®ABS& CORE is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ABS& CORE may be considered a technique or method for muscle training. 2-area belt is intended for use on the muscles in abdomen or lower back separately. Mini belt is intended for use on the muscles in arms, legs, thighs or buttocks areas separately	"HIVOX OTC Electrical Stimulator, SEM44 – TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise o normal household work activities. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance"	SE NOTE 4
Location for use	OTC	OTC	OTC	SE
BASIC UNIT SPECIFICATIOSN				
Power supply	2032 Button battery (DC3V)	2 ×1.5V AAA batteries	4.5V (batteries, 3×1.5V AAA)	SE

Comparison Elements		**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
					NOTE 1
Number of output modes		3	6	TENS: 15 EMS: 35	SE NOTE 1
Number of output channels	Channel Number	1	2	2	SE NOTE 1
	Synchronous or Alternating?	N/A	Alternating	Synchronous	SE
	Method of Channel Isolation	N/A	Press MODE button for 3 seconds	By electrical circuit and software	SE
Regulated Current or Voltage?		Regulated Voltage	Regulated Voltage	Regulated Voltage	SE
Software/Firmware /Microprocessor Control?		Yes	Yes	Yes	SE
Automatic overload trip voltage level?		No	No	Yes	SE
Automatic no-load trip?		Yes	Yes	Yes	SE
Automatic shut off		Yes	Yes	Yes	SE

Comparison Elements		**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
Patient override control?		Yes	Yes	Yes	SE
Indicator Display	On/Off Status?	Yes	Yes	Yes	SE
	Low Battery?	Yes	Yes	Yes	SE
	Voltage/ Current Level?	N/A	Yes	Yes	SE
Timer range		Default 15-minute	Default 10-minute	5-100 minutes	SE
Compliance with voluntary standards		■ IEC60601-1-2 ■ IEC60601-1 ■ IEC60601-1-11 ■ IEC60601-2-10	■ IEC60601-1-2 ■ IEC60601-1 ■ IEC60601-2-10	■ IEC60601-1-2 ■ IEC60601-1 ■ IEC60601-2-10	SE
Compliance with 21CFR 898		Yes	Yes	Yes	SE
Dimensions (L*W*H)		(Host) KTR-230 series: ø51×13.5mm KTR-231: ø51×13.5mm KTR-232: ø51×13.5mm KRT-233: 53.4×47.5×11.8mm KTR-234: 49×49×12.6mm	100mm×68mm×24.5mm	132mm×63mm×29.5mm (including belt clip)	SE NOTE 2
Weight		(Host) KTR-230 series: 0.6oz KTR-231: 0.6oz KTR-232: 0.6oz KTR-233: 0.6oz	50g (Without batteries)	89g (including belt clip, without batteries) 123g (including belt clip and batteries)	SE NOTE 2

Comparison Elements	**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
	KTR-234: 0.56oz			
Housing material and construction	ABS	ABS	ABS	SE
OUTPUT SPECIFICATIOSNS				
Waveform	Mode 1: Pulsed symmetric, biphasic, square wave Mode 2: Pulsed symmetric, biphasic, square wave Mode 3: Pulsed symmetric, biphasic, square wave	Symmetrical, rectangular	Biphasic, square	SE
Maximum output voltage	Mode 1: (±10%)Vp 36.5V @500Ω 58.5V @2kΩ 93 V @10kΩ Mode 2: (±10%)Vp 36.5V @500Ω 58.5V @2kΩ 93 V @10kΩ Mode 3: (±10%)Vp 36.5V @500Ω 58.5V @2kΩ 93 V @10kΩ	(±10%)Vp 66V @ 500 Ω 69V @ 2k Ω 70V @ 10k Ω	(±10%)Vp 50V @ 500 Ω 60V @ 2k Ω 125V @ 10k Ω	SE NOTE 3
Maximum output	Mode 1: (±10%) Ip	(±10%)Ip 132mA @ 500 Ω	(±10%)Ip 100mA @ 500 Ω	SE NOTE 3

Comparison Elements	**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
current	73mA @ 500 Ω 29.25mA @ 2k Ω 9.3mA @ 10k Ω Mode 2: (±10%) Ip 73mA @ 500 Ω 29.25mA @ 2k Ω 9.3mA @ 10k Ω Mode 3: (±10%) Ip 73mA @ 500 Ω 29.25mA @ 2k Ω 9.3mA @ 10k Ω	34.5mA @ 2k Ω 7mA @ 10k Ω	45mA @ 2k Ω 12.5mA @ 10k Ω	
Net charge (per pulse)	@500Ω Mode 1: 0 Mode 2: 0 Mode 3: 0	19.2μC @ 500 Ω	0.001μC @ 500 Ω	SE
Maximum phase charge @500Ω	Mode 1: 6.85μC@500 Ω Mode 2: 10.11μC@500 Ω Mode 3: 10.11μC@500 Ω	16.4μC @ 500 Ω	0.045μC @ 500 Ω	SE NOTE 3
Maximum average current @500Ω	Mode 1: 3.6mA@500 Ω Mode 2: 1.1mA@500 Ω Mode 3: 5.4mA@500 Ω	2.304mA@500 Ω	13.5mA @ 500 Ω	SE NOTE 3
Maximum current density @500Ω	Mode 1: KTR-230series: 0.175mA/cm^2@500 Ω KTR-231: 0.050mA/cm^2@500 Ω KTR-232: 0.073mA/cm^2@500 Ω	0.082mA/ cm2@ 500 Ω	0.667mA/ cm2@ 500 Ω	SE NOTE 3

Comparison Elements	**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
	KTR-233: 0.169mA/cm^2@500 Ω KTR-234: 0.172mA/cm^2@500 Ω Mode 2: KTR-230series: 0.053mA/cm^2@500 Ω KTR-231: 0.015mA/cm^2@500 Ω KTR-232: 0.022mA/cm^2@500 Ω KTR-233:0.052mA/cm^2@500 Ω KTR-234: 0.053mA/cm^2@500 Ω Mode 3: KTR-230series: 0.263mA/cm^2@500 Ω KTR-231: 0.076mA/cm^2@500 Ω KTR-232: 0.109mA/cm^2@500 Ω KTR-233: 0.254mA/cm^2@500 Ω KTR-234: 0.258mA/cm^2@500 Ω			
Maximum power density @500Ω	Mode 1: KTR-230series: 0.0003W/cm^2@500 Ω KTR-231: 0.00009W/cm^2@500Ω KTR-232: 0.0001W/cm^2@500Ω KTR-233: 0.0003W/cm^2@500Ω KTR-234: 0.0003W/cm^2@500Ω Mode 2: KTR-230series: 0.00003W/cm^2@500 Ω KTR-231: 0.000008W/cm^2@500Ω	94.8μW/cm2 @ 500 Ω	0.0046μW/cm2 @ 500 Ω (average)	SE NOTE 3

Comparison Elements		**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
		KTR-232: 0.00001W/cm^2@500Ω KTR-233: 0.00003W/cm^2@500Ω KTR-234: 0.00003W/cm^2@500Ω Mode 3: KTR-230series: 0.0007W/cm^2@500Ω KTR-231: 0.0002W/cm^2@500Ω KTR-232: 0.0003W/cm^2@500Ω KTR-233: 0.0007W/cm^2@500Ω KTR-234: 0.0007W/cm^2@500Ω			
Pulse frequency		Mode 1: 1-120Hz Mode 2: 1-120Hz Mode 3: 1-120Hz	2Hz, 10Hz, 50Hz, 90Hz, 120Hz	1-150Hz	SE NOTE 3
Pulse duration		Mode 1: 50-200μs Mode 2: 50-200μs Mode 3: 50-200μs	108μs/124μs	50-450μs	SE NOTE 3
Burst Mode	Pulses per burst	Mode 1: N/A Mode 2: N/A Mode 3: N/A	1~397	3	SE
	Bursts per second	Mode 1: N/A Mode 2: N/A Mode 3: N/A	0.125~1	2/60Hz	SE
	Burst duration (seconds)	Mode 1: N/A Mode 2: N/A Mode 3: N/A	1~8	36ms	SE
	Duty Cycle	Mode 1: N/A Mode 2: N/A	0.02%~1.28%	36ms/390ms	SE

Comparison Elements	**Subject Device**	**Primary Predicate Device K142055**	**Predicate Device 1 K171803**	
[Line (b) x Line (c)]	Mode 3: N/A			
ON Time (seconds)	1s	0.5s	2s	SE
OFF Time (seconds)	<3s	0.5s	2s	SE
ADDITIONAL FEATURES				
Environment for Operation	Temperature: 5℃~40℃ Humidity: 15%~93%RH	Temperature: 5℃~40℃ Humidity: 20%~65%RH	Unknown	SE
Environment for Storage	Temperature: -25℃~70℃ Humidity: 0%~93%RH	Temperature: 0℃~40℃ Humidity: 10%~90%RH	Unknown	SE
Environment for Transport	Temperature: -10℃~40℃ Humidity: 15%~93%RH	Unknown	Unknown	SE

COMPARISON IN DETAILS:

NOTE 1: Although the Power supply, Number of output modes, Output Intensity Level, Number of output channels and Timer range of the subject devices are a little different from the predicate devices, they are all compliant with the requirements of IEC60601-1-2, IEC60601-1 and Guidance for Powered Muscle Stimulator. So the device does not raise different questions of safety and effectiveness as compared to the predicate devices.

NOTE 2: Although the appearance, weight and dimensions are different between the subject devices and predicate device, these differences are insignificant and do not affect safety and effectiveness.

NOTE 3: Although the Maximum output voltage, Maximum output current, Maximum average current, Maximum phase charge, Maximum current density, Maximum power density, Pulse frequency and Pulse duration of the subject devices are a little different from the predicate devices, but all are within the range of the predicates and they are all compliant with the requirements of IEC60601-1, IEC60601-2-10, and Guidance for Powered Muscle Stimulator. So the device does not raise different questions of safety and effectiveness as compared to the predicate devices.

NOTE 4: The intended use (indication of use) of the subject device is within the scope of the predicate device K142055, and is the same with the predicate device K171803, model SEM44, mode EMS. This define does not affect the intended use or normal use of the subject device.

CONCLUSION: The subject device Muscle Trainer is substantial equivalent to the predicate devices.

VII.Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The component of the Muscle Trainer that directly contacting the user is electrode patches and support belt.

Component Name	Material of Component	Body Contact Category	Contact Duration
Electrode patches	EVA foam, Carbon film, conductive hydrogel, PET	Surface-contacting skin	Less than 24hours

The electrode patches are directly purchased from qualified supplier which has obtained FDA clearance with a 510(k) number of K171381 and been legally marketed to U.S. market.

2) Electrical and EMC Safety

Electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 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 Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests

In addition to the compliance of voluntary standards:

- The software verification has been carries out according to the FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.
- The waveform test report has also been conducted to verify the output specifications of the subject device according to the FDA Guidance for Powered Muscle Stimulator 510(k)s: Load conditions of 0.5kΩ, 2kΩ and 10kΩ were tested, graphic waveform, output level and maximum charge/current/power calculation is recorded in this report. The outputs of the device models all are biphasic pulsed symmetric waveform, and have the same output design, such as output voltage and current, frequency, pulse duration and so on.
- The verification report of dispersion and shelf life has been conducted to verify the current dispersion and shelf life of the electrode patch equipped according to the FDA Guidance Shelf Life of Medical Device and ASTM F 1980-07 standard:
  1) Under the specified conditions, test and record the current dispersion of electrode patch and check the impedance on several places of the active areas of the patch to ensure it is distributing current uniformly, as well as the shelf life and the service life of the electrode patch are judged by comparing the test results. All test results are passed.
  2) First the data and analysis from Electrode patch dispersion and shelf life testing of KTR-231 and KTR-230 proves that there is no significant difference between the impedances of each point of 6 electrode patches connected to 1 channel, which is the same as 2 electrode patches to 1 channel. That means the current dispersion of each point of 6 electrode patches distributes uniformly. Therefore, 6 patches only differ in area from 2 patches, which are equivalent to 1 large pad made of 6 single same patches together. Second the maximum current density of model KTR-231, decided by the quantity and area of electrode pads, voltage, is less than 0.6(W/cm^2). Third KTR-231 complies with the requirements of IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10. Therefore, the difference does not present different questions of safety.
  3) Moreover, it is not the specifications about effectiveness, the maximum output voltage and current of model KTR-231 is equivalent to predicate device, thus the difference does not present different questions of effectiveness.

Summary

Based on the above performance as documented in this application, Muscle Trainer was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

The subject device Muscle Trainer is to be concluded substantial equivalent to its predicate devices.