DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 11, 2017

Shenzhen Kentro Medical Electronics Co., Ltd
Tracy Che
Application Correspondent
No.3, Xihu Industry Zone, Xikeng Village, Henggang Town
Longgang District
Shenzhen City, 518115 CN

Re: K170205
Trade/Device Name: Low-Frequency Therapy Instrument /Model: KTR-201, KTR-202, KTR-203
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: April 24, 2017
Received: April 26, 2017

Dear Tracy Che:

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,

William J. Heetderks -S

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.05.11 13:55:48 -04'00'

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)*
K170205

Device Name
Low-Frequency Therapy Instrument/Model: KTR-201, KTR-202, KTR-203

Indications for Use *(Describe)*
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, leg and foot, due to strain from exercise or normal household and work activities

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

K170205

(1) Applicant information:

510(k) owner's name:	SHENZHEN KENTRO MEDICAL ELECTRONICS CO., LTD
Address:	No.3, Xihu Industry Zone, Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China
Contact person:	Zewu Zhang
Phone number:	+86 755 3382 5998
Fax number:	+86 755 3382 5996
Email:	kentro@kentro.com.cn
Date of summary prepared:	May 4, 2017

(2) Proprietary name of the device

Trade name/model:	Low-Frequency Therapy Instrument /Model: KTR-201, KTR-202, KTR-203
Common name:	Transcutaneous Electrical Nerve Stimulator
Regulation number:	21CFR 882.5890
Product code:	NUH
Review panel:	Neurology
Regulation class:	Class II

(3) Predicate devices

Sponsor	Shenzhen OSTO Technology Company Limited	Endurance Therapeutics	Tyece Ltd.	M.i.tech Co., Ltd.
Device Name and Model	Health Expert Electronic Stimulator, Model AST-300C and AST-300D	T1040 aka Aurawave	Tyece OTC TENS Device, Model SEM44	HANAROCare ReJu
510(k) Number	K133929	K124055	K150386	K160893
Product Code	NUH, NGX	NUH, NYN, NGX, GZJ	NUH	NUH
Regulation	21 CFR 882.5890	21 CFR 882.5890	21 CFR	21 CFR

Number			882.5890	882.5890
Regulation Class	II	II	II	II

(4) Description/ Design of device:

The Low-Frequency Therapy Instrument is a product that adopts modern electronic science and technology to produce low-frequency electrical pulse and transmit that through the skin to the underlying peripheral nerves by electrodes, in order to reach the therapeutic aim.

There are three models of Low-Frequency Therapy Instrument which are KTR-201, KTR-202, KTR-203. Their technical parameters are slightly different, but they share the basically same characteristics: 1) They are small, and exquisite; 2) they have different treatment modes which can satisfy various demands, thus can be used by a wider range of people; 3) LCD display with a big screen makes the operation easy and clear, and the contents displayed on LCD can guide the treatment.

The Low-Frequency Therapy Instrument is mainly composed of the host and electrode patches and it uses AAA batteries for power supply. To start therapy, first insert batteries, then paste the electrode patches onto treatment areas and press power button to turn the power on. The modes and intensity can be selected according to needs. The current status is displayed on LCD.

(5) Intended use / indications:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, leg and foot, due to strain from exercise or normal household and work activities.

(6) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Electrode patches	Hydrogel	Surface skin contact	Less than 24 hours

We have directly purchased electrode patches from qualified supplier which has obtained FDA clearance with a 510(k) number of K152815 and been legally marketed to US market. For details, please refer to "Biocompatibility Discussion".

(7) Technological characteristics and substantial equivalence:

Parameters	Subject device (K170205)	Primary predicate device (K133929)	Remark
Trade name	Low-Frequency	Health Expert	N/A

	Therapy Instrument (Model: KTR-201, KTR-202, KTR-203)	Electronic Stimulator, Model: AST-300C and AST-300D	
Indications for Use	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, leg and foot, due to strain from exercise or normal household and work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	Similar
Regulation number	21 CFR 882.5890	21 CFR 882.5890	Identical
Product code	NUH	NUH, NGX	Similar
Class	II	II	Identical
OTC/Rx	OTC	OTC	Identical
Basic unit specifications			
Power supply	KTR-201: DC 3V, 30 mA KTR-202: DC 4.5V, 100 mA KTR-203: DC 3V, 30mA	100-240VAC, 50-60Hz, 0.1A	Predicate is powered by mains supply but does not affect safety and effectiveness of subject device
Output modes	KTR-201: 10 KTR-202:10 KTR-203: 5	25	Identical
Output channels	KTR-201: 1 KTR-202:1 KTR-203: 2	2	Similar. Does not affect safety and effectiveness of subject device.
Software	Yes	Yes	Identical
Automatic Shut off	Yes	Yes	Identical
Timer range	15 mins	25 mins	Different but does not affect safety and effectiveness of subject device.
Dimensions	KTR-201: 147mm x 59mm x 27.5mm KTR-202: 151mm x	428mm x 428.8mm x 185mm	Not applicable

	100mm x 46mm KTR-203: 98.9mm x 64mm x 31.25mm		
Weight	KTR-201 (Host): 2.7oz KTR-202 (Host): 5.7oz KTR-203 (Host): 1.7oz	70.5oz (2kg) (without accessories)	Not applicable
Housing material and construction	ABS	ABS	Identical
Compliance with voluntary standards	IEC60601-1; IEC60601-1-2; IEC60601-1-11; IEC-60601-2-10	IEC60601-1; IEC60601-1-2; IEC-60601-2-10; ISO10993-5; ISO10993-10	Similar
Compliance with 21 CFR 898	Yes	Yes	Identical
Output specifications			
Waveform	Pulsed symmetric, biphasic, square wave	Pulse symmetric, biphasic, rectangular with interphase interval	Similar
Maximum output voltage (V_p)	44V@500ohm 58V@2kohm 63.5V@10kohm	44V±10%@500ohm 80V±10%@2kohm 112V±10@10kohm	Similar
Maximum output current	88mA@500ohm 29mA@2kohm 6.35mA@10kohm	88mA±10%@500ohm 40mA±10%@2kohm 11.2mA±10%@10kohm	Similar
Net charge (per pulse)	0µC @500ohm	0µC @500ohm	Identical
Maximum phase charge	11.7µC @500ohm	12.78µC@500ohm	Similar
Maximum Average Current (500ohm)	7.4mA	0.968mA	Although the maximum average current is different, it is <10mA, which complies with the requirements of IEC 60601-2-10, so the difference does not affect safety and effectiveness of the subject device.
Maximum current density	0.15mA/cm^2@500ohm	0.235mA/cm^2@500ohm	Current density is <2mA/cm^2 which complies with the

			requirements of IEC 60601-2-10, so the difference does not affect safety and effectiveness of the subject device.
Maximum power density	0.56mW/cm^2@500ohm	1.38mW/cm^2@500ohm	Power density is <0.25W/cm^2 and does not affect safety and effectiveness of the subject device
Pulse frequency	1-200Hz	77.3Hz	Similar
Pulse duration	50-220us	120us	Similar
ON time	No	0.6s	Does not affect safety and effectiveness of subject device
OFF time	No	0.6s	Does not affect safety and effectiveness of subject device

(8) Non-clinical studies and tests performed:

Non-clinical tests have been conducted to verify that the low-frequency therapy instrument meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

- IEC60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC60601-1-11, 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
- IEC60601-2-10, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

The body-contacting components of this device are electrode patches. We have directly purchased the electrode patches from qualified supplier which has obtained FDA clearance with a 510(k) number of K152815 and been marketed to US market. So we have reason to believe that the electrode patches are safe for the users. The electrode patches comply to the following standards.

- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- The waveform test report has also been conducted to verify the output specifications of the device according to Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use

(9) Conclusion

Based on the above analysis and tests performed, it can be concluded that the performance and function of Low-Frequency Therapy Instrument are normal, safe and effective, and it is Substantially Equivalent (SE) to the predicate devices.