July 30, 2019

Shenzhen Kentro Medical Electronics Co., Ltd
℅ Tracy Che
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
B-3F-3005, Bldg.1, Southward Ruifeng Business Center, No.22
Guimiao Rd.
Shenzhen, 518000 Cn

Re: K183288
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator (Models: KTR-206, KTR-208, KTR-209)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: June 3, 2019
Received: June 5, 2019

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K183288

Device Name
Transcutaneous Electrical Nerve Stimulator (KTR-206, KTR-208, KTR-209)

Indications for Use *(Describe)*
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, arm, leg, 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

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(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:	March 1, 2019

(2) Proprietary name of the device

Trade name/model:	Transcutaneous Electrical Nerve Stimulator/ KTR-206, KTR-208, KTR-209
Common name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation number:	21 CFR 882.5890
Product code:	NUH
Review panel:	Neurology
Regulation class:	Class II

(3) Predicate and reference devices

❖ Predicate device

Sponsor	Easymed Instruments Co., Ltd
Device Name and Model	EasyStim TN28_OTC
510(k) Number	K140168
Product Code	NUH
Regulation Number	21 CFR 882.5890
Regulation Class	II

❖ Reference device

Sponsor	Shenzhen OSTO Technology Company Limited	DJO, LLC	Omron Healthcare, Inc.
Device Name	Health Expert Electronic	Compex® Wireless	Avail, Model

and Model	Stimulator, Model: AST-300C and AST-300D	USA	PM601
510(k) Number	K133929	K170903	K172079
Product Code	NUH, NGX	NUH, NGX, NYN	NUH, NYN
Regulation Number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
Regulation Class	II	II	II

(4) Description/ Design of device:

Transcutaneous Electrical Nerve Stimulator is a product that adopts modern electronic science and technology to deliver electric pulses generated to the user's skin through the electrodes.

There are three models of Transcutaneous Electrical Nerve Stimulator which are KTR-206, KTR-208 and KTR-209. Their technical parameters are slightly different, but they share the basically same characteristics: 1) They are small, exquisite and portable; 2) various modes to satisfy different demands, applicable to a wider range of people; 3) wonderful electric pulse combination, 0~16 levels can be adjusted and chosen according to personal preference; 4) LCD display make the operation simple and easy; 5) integrated design of the body is easy for function operation and simple in practical use; 6) battery power display; 7) dual channel output, user can cover more treatment areas. For KTR-208 and KTR-209, the two channels are independently controlled for intensity adjustment which is more convenient to use.

The Transcutaneous Electrical Nerve Stimulator 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 painful areas and press on/off button to power on. The modes and intensity can be selected according to needs. And 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, back, arm, leg, 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	EVA foam, carbon	Surface skin contact	Less than 24 hours

	film, hydrogel, PET		

We have directly purchased the electrode patches from qualified supplier which has obtained FDA clearance with a 510(k) number of K171381 and been legally marketed to US market. For details, please refer to "Biocompatibility Discussion".

(7) Technological characteristics and substantial equivalence:

Item	Targeted device	Predicate device	Reference device 1	Reference device 2	Reference device 3	Remark
Trade name	Transcutaneous Electrical Nerve Stimulator	EasyStim TN28_OTC	Health Expert Electronic Stimulator, Model: AST-300C and AST-300D	Compex® Wireless USA	Avail Model PM601	/
510 (k) number	K183288	K140168	K133929	K170903	K172079	/
Regulation number	21 CFR 882. 5890	21 CFR 882. 5890	21 CFR 882. 5890	21 CFR 882. 5890	21 CFR 882. 5890	Same
Regulation description	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous Electrical Nerve Stimulator For Pain Relief	Same
Product code	NUH	NUH	NUH, NGX	NUH, NGX, NYN	NUH, NYN	Same
Class	II	II	II	II	II	Same
Indications for use/ Intended use	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, arm, leg, foot, due to strain from exercise or	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from	TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the	The Compex Wireless USA TENS is used for: • temporary relief of pain associated with sore and aching muscles due to strain from exercise or	The Avail is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders	Similar

	normal household and work activities.	exercise or normal household and work activities.	neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	normal household and work activities. • the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	or feet due to strain from exercise or normal household work activities. When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Tap, Shoulder, Arm or Leg mode of stimulation. Environments of Use: Clinics, hospital and home environments Patient Population: Adult	
Patient population	Adult	Adult	Adult	Adult	Adult	Same
Location for use	OTC	OTC	OTC	OTC	OTC	Same
Basic unit specifications						
Power supply	KTR-206: 2 AAA batteries (DC	2 Alkaline AA 1.5V (LR6)	Adaptor Input: 100-240Vac,	Remote: : Lithium Polymer	Rechargeable Lithiumion	Similar

	3V) KTR-208: 2 AAA batteries (DC 3V) KTR-209: AAA LR03 battery ×3 (DC 4.5V)	Batteries	50-60Hz, 0.1A Output:5Vdc, 1A Unit Input: 5Vdc,1A	(LiPo) rechargeable 3.7[V] / ⩾ 1500[mAh Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ⩾ 450[mAh]	battery	
Leakage current	N/A (Battery operated)	/	AC: 54.5μA, DC: 0.5μA (NC)/ AC:120.0μA, DC: 0.6μA (SFC)	N/A (Battery operated)	Normal Condition (uA): <10uA Single Fault Condition (uA): <50uA	Same
Number of output modes	5	8	25	2	9 TENS modes; 1 Microcurrent mode	Different Note 1
Number of output channel	2	2	2	4	1	Same
-Synchronous or Alternating?	KTR-206: Synchronous KTR-208/ KTR-209: Alternating	Alternating	Synchronous	Synchronous, but never 2 channels activated at the same time.	N/A	Similar
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
Automatic Overload trip	No	Yes	No	Yes	No	Same
Automatic no-load trip	Yes	Yes	No	Yes	Yes	Same
Patient override	On/Off button	/	Yes	Yes, push on On/Off button	Yes, Power On/Off	Similar

control method				directly pause the program.	button on the device and in the App software.	
Indicator display -On/Off status -Low battery -Output mode -Time to cut-off	 Yes Yes Yes Yes	 Yes Yes Yes Yes	 Yes No Yes Yes	 Yes Yes / /	 Yes on App and LED indicator on main unit. Yes on App / /	Same
Automatic Shut Off	Yes	Yes	Yes	No	Yes	Same
Timer range	15min default KTR-206: 5/10/15min KTR-208:5/10/15/20/25/30 min KTR-209:5/10/15/20/25/30 min	20min, 25min, 30min, 40min depending on preset program	25min	/	5-60minutes and 30-180 minutes	Similar
Dimensions	KTR-206: 112.5*59*33.3mm KTR-208: 112.5*59*29.5mm KTR-209: 129.7*60*17.8mm	66×136×30.7 mm	428mm × 428.8mm × 185mm	/	Device: Approx. 60 × 72 × 15.5mm (Both units have same dimensions) Charger: Approx. 158 × 90 × 20.5mm Pad-L: Approx. 219 × 83.5 × 9.3mm	Different Note 2

					Pad-M: Approx. 180 × 79.5 × 9.3mm	
Weight	KTR-206: 1.68oz KTR-208: 1.79oz KTR-209: 2.7oz	146.5 grams	70.5oz (2Kg) (Without accessories)	Remote:110 [g]; Stimulation Module:2x60[g]; Docking Station 800 [g]	Device: Approx. 42g (Both units have same weight) Pad-L: Approx. 21g Pad-M: Approx. 17.5g Charger: Approx. 100g	Different Note 2
Housing material and construction	ABS	ABS	ABS	/	/	Same
Compliance with voluntary standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11.	AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11.	IEC60601-1; IEC60601-1-2; IEC-60601-2-10; ISO10993-5; ISO10993-10	AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11.	ES 60601-1, IEC 60601-1- 2, IEC 60601-2-10, IEC 60601-1- 11	Similar
Compliance with 21CFR 898	Yes	Yes	Yes	Yes	N/A	Same
Output specifications						
Waveform	Biphasic, Pulsed symmetric, square wave	Biphasic , Monophasic, Rectangular wave	Pulsed symmetric, biphasic, rectangular with interphase interval	Balanced, asymetrical Biphasic, Rectangular wave	Biphasic , Rectangular wave	Similar
Maximum	KTR-206: 49.6V@ 500Ω	68V@500oh	44V±10%@	58V@500ohm	38.4V@500	Similar

output voltage	68.5V @ 2kΩ 73V @ 10kΩ KTR-208: 58.5V @ 500Ω 70V @ 2kΩ 70.5V @ 10kΩ KTR-209: 62V @ 500Ω 80V @ 2kΩ 84V @ 10kΩ	ms 102V@2kohms 110V@10kohms	500Ω 80V±10%@ 2kΩ 112V±10%@ 10kΩ	s 170V@2kohms 180V@10kohms	Ω 50.8V@2kΩ 59.9V@10kΩ	
Maximum output current	KTR-206: 99.2mA @ 500Ω 34.25mA @ 2kΩ 7.3mA @ 10kΩ KTR-208: 117mA @ 500Ω 35mA @ 2kΩ 7.05mA @ 10kΩ KTR-209: 124mA @ 500Ω 40mA @ 2kΩ 8.4mA @ 10kΩ	133mA@500ohms 51mA@2kohms 11mA@10kohms	88mA±10% @ 500Ω 40mA±10% @ 2kΩ 11.2mA±10% @ 10kΩ	116mA@500ohms 86mA@2kohms 18mA@10kohms	76.8mA@ 500Ω 25.4mA@ 2kΩ 6.0mA@ 10kΩ	Similar
Net Charge (per pulse)	0	/	0	0	0	Same
Maximum Phase Charge (500Ω)	KTR-206: 12.32μC KTR-208: 18.12μC KTR-209: 33.07μC	20.02μC	12.78μC	48μC	7.37μC	Similar
Maximum Average Current(500Ω)	KTR-206: 8.04mA KTR-208: 6.89mA	3.0375mA	0.968mA	/	0.98mA	Different Note 3

	KTR-209: 12.39mA					
Maximum current density (500Ω)	KTR-206: 0.26mA/ cm^2	0.188mA/cm^2	0.235mA/ cm^2	4.8mA/cm^2	0.17mA/ cm^2	Similar
	KTR-208: 0.22mA/ cm^2					
	KTR-209: 0.4mA/ cm^2					
Maximum power density (500Ω)	KTR-206: 0.001W/ cm^2	0.00752W/cm^2	1.38W/cm^2	0.0276W/cm^2	0.0006769 W/cm^2	Similar
	KTR-208: 0.0008W/ cm^2					
	KTR-209: 0.0025W/ cm^2					
Pulse frequency	KTR-206: 1 Hz-108Hz	1-150Hz	77.3Hz	5-122Hz	1-108Hz	Similar
	KTR-208: 1 Hz-109Hz					
	KTR-209: 1 Hz-110Hz					
Pulse duration	KTR-206: 84μs-134μs	50-250μs	120μs	70-300μs	96μs	Similar
	KTR-208: 82μs-128μs					
	KTR-209: 80μs-224μs					

Comparison in details:

Note 1:

Although the number of output is different from that of the predicate, we have tested the output parameters of each mode, and the targeted device has passed IEC 60601-1 and IEC 60601-2-10, so this difference does not affect safety and effectiveness.

Note 2:

Although the appearance, weight and dimensions are different between the targeted and predicate devices, these differences are insignificant and do not affect safety and effectiveness.

Note 3:

Although the maximum average currents are different between the targeted and predicate devices, those are all ＜50mA, which comply with the requirements of IEC 60601-2-10 (clause 201.12.4.104), so the difference does not affect safety and effectiveness.

Conclusion:

Transcutaneous Electrical Nerve Stimulator is substantial equivalent to the predicate

device.

(8) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the Transcutaneous Electrical Nerve Stimulator 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:

- IEC 60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- 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

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 K171381 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 with 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 Transcutaneous Electrical Nerve Stimulator are normal, and it is Substantially Equivalent (SE) to the predicate device.