August 24, 2022

Shenzhen Kentro Medical Electronics Co., Ltd.
℅ Yvonne Liu
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center,
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K220998
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator, Model: KTR-405
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, IPF, NYN, GZJ
Dated: July 12, 2022
Received: July 18, 2022

Dear Yvonne Liu:

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,

for Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220998

Device Name
Transcutaneous Electrical Nerve Stimulator, Model: KTR-405

Indications for Use *(Describe)*

1) When using Electrical Muscle Stimulation, Transcutaneous Electrical Nerve Stimulator is intended:

- for users with conditions or disease that are associated with impaired (poor) blood flow in the legs/ ankles/ feet, the device through the foot-pads is intended for use as an adjunctive treatment (as an addition to your existing treatment) to temporarily reduce lower extremity pain, swelling and cramping
- to temporarily increase local blood circulation in healthy leg muscles
- to stimulate healthy muscles in order to improve and facilitate muscle performance
- to temporarily relieve pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities(legs) due to strain from exercise or normal household duties
- to relax muscle spasm
- to increase blood flow circulation
- for prevention of retardation of disuse atrophy
- for muscle re-education
- for maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Provide quadricep strengthening
- Improve knee stability secondary to quadricep strengthening

2) When using Transcutaneous Electrical Nerve Stimulator to deliver Transcutaneous Electrical Nerve Stimulation (TENS), it is intended to provide:

- symptomatic relief and management of chronic, intractable pain
- relief of pain associated with arthritis
- temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K220998

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:	2nd Floor No 11, Shanzhuang Road, Xikeng Village,Yuanshan Street, Longgang District, Shenzhen City, Guangdong Province,China
Contact person:	Zewu Zhang
Phone number:	+86 755 3382 5998
Fax number:	+86 755 3382 5996
Email:	522378976@qq.com
Date of summary prepared:	August 24, 2022

(2) Reason for submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	Transcutaneous Electrical Nerve Stimulator/ KTR-405
Common name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter; Stimulator, Muscle, Powered, For Muscle Conditioning; Stimulator, Muscle, Powered; Stimulator, Electrical, Transcutaneous, For Arthritis; Stimulator, Nerve, Transcutaneous, For Pain Relief
Regulation number:	21 CFR 882.5890, 890.5850
Product code:	NUH, NGX, IPF, NYN, GZJ
Review panel:	Neurology, Physical Medicine
Regulation class:	Class II

(4) Predicate device

	Predicate device
Sponsor	ACTEGY LTD
Device Name and Model	Revitive Medic Coach Model: 5575AQ

510(k) Number	K210825
Product Code	NGX, NUH, IPF, NYN, GZJ
Regulation Number	21 CFR 890.5850, 882.5890
Regulation Class	II

(5) 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.

The proposed model KTR-405 provides a combination of transcutaneous electrical nerve stimulation (TENS) and electrical muscle stimulation (EMS). It has the following basic characteristics: 1) 10 modes to satisfy different demands. Modes 1-8 are for foot and can be switched to another mode for a minute automatically, while mode 9 is for knee and mode 10 for body. Modes for foot, knee and body can be switched manually during a session; 2) wonderful electric pulse combination, 0~150 levels can be adjusted and chosen according to personal preference; 3) rechargeable battery which can work up to 36 hours 4) wireless and rechargeable remote control allows easy control of the device 5) use while seated or reclining with Relax and Recline mode; 6)foot cover helps keep feet warm and cosy; 7) LCD display and power display make the operation simple and easy; 8) carry handle for easy transportation; 9) magnetic power cable for simple and safe connection.

Transcutaneous Electrical Nerve Stimulator is mainly composed of the host and electrode patches. And it can be run either from the mains power supply or via its internal rechargeable battery. To start therapy, you need to connect the device to the mains power supply. This will charge the battery, allowing you to use the device wirelessly in subsequent sessions.Then while seated, place both your bare feet onto the footpads of the device or paste the electrode pads 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.

(6) Intended use / indications:

1) When using Electrical Muscle Stimulation, Transcutaneous Electrical Nerve Stimulator is intended:

● for users with conditions or disease that are associated with impaired (poor) blood flow in the legs/ ankles/ feet, the device through the foot-pads is intended for use as an adjunctive treatment (as an addition to your existing treatment) to temporarily reduce lower extremity pain, swelling and cramping

● to temporarily increase local blood circulation in healthy leg muscles

● to stimulate healthy muscles in order to improve and facilitate muscle performance

● to temporarily relieve pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
● to relax muscle spasm
● to increase blood flow circulation
● for prevention of retardation of disuse atrophy
● for muscle re-education
● for maintaining or increasing range of motion
● Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
● Provide quadricep strengthening
● Improve knee stability secondary to quadricep strengthening

2) When using Transcutaneous Electrical Nerve Stimulator to deliver Transcutaneous Electrical Nerve Stimulation (TENS), it is intended to provide:
● symptomatic relief and management of chronic, intractable pain
● relief of pain associated with arthritis
● temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Electrode pads	EVA foam, carbon film, hydrogel, PET	Surface skin contact	Less than 24 hours
Foot pads	Silica gel	Surface skin contact	Less than 24 hours

We have directly purchased the electrode pads from qualified supplier which has obtained FDA clearance with a 510(k) number of K171381 and been legally marketed to US market. Also we've conducted biocompatibility tests for foot pads and all pass. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence

Item	Subject device	Predicate device	Remark
Trade name	Transcutaneous Electrical Nerve Stimulator Model: KTR-405	Revitive Medic Coach Model: 5575AQ	/
510 (k) number	K220998	K210825	/
Regulation number	21 CFR 882.5890, 890.5850	21 CFR 882.5890, 890.5850	Same
Regulation description	Transcutaneous electrical nerve stimulator for pain relief; powered muscle stimulator	Transcutaneous electrical nerve stimulator for pain relief; powered muscle stimulator	Same
Product code	NUH, NGX, IPF, NYN, GZJ	NGX, NUH, IPF, NYN, GZJ	Same
Class	II	II	Same
Indications for use/ Intended use	1) When using Electrical Muscle Stimulation, Transcutaneous Electrical Nerve Stimulator is intended: ● for users with conditions or disease that are associated with impaired (poor) blood flow in the legs/ ankles/ feet, the device through the foot-pads is intended for use as an adjunctive treatment (as an addition to your existing treatment) to temporarily reduce lower extremity pain, swelling and cramping ● to temporarily increase local blood circulation in healthy leg muscles ● to stimulate healthy muscles in order to improve and facilitate muscle performance ● to temporarily relieve pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties ● to relax muscle spasm	When using Electrical Muscle Stimulation (NMES), Revitive is intended: ●for users with conditions or disease that are associated with impaired (poor) blood flow in the legs/ ankles/ feet, NMES though the foot-pads is intended for use as an adjunctive treatment (as an addition to your existing treatment) to temporarily reduce lower extremity pain, swelling and cramping ●to temporarily increase local blood circulation in healthy leg muscles ●to stimulate healthy muscles in order to improve and facilitate muscle performance ●to temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities(legs) due to strain from exercise or normal household duties ●for relaxation of muscle spasm, ●for increase of blood flow	Same

	● to increase blood flow circulation ● for prevention of retardation of disuse atrophy ● for muscle re-education ● for maintaining or increasing range of motion ● Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis ● Provide quadricep strengthening ● Improve knee stability secondary to quadricep strengthening 2) When using Transcutaneous Electrical Nerve Stimulator to deliver Transcutaneous Electrical Nerve Stimulation (TENS), it is intended to provide: ● symptomatic relief and management of chronic, intractable pain ● relief of pain associated with arthritis ● temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties	circulation, ●for prevention of retardation of disuse atrophy, ●for muscle re-education, ●for maintaining or increasing range of motion,and ●Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis ●Provide quadricep strengthening ●Improve knee stability secondary to quadricep strengthening (2) When using Revitive to deliver Transcutaneous Electrical Nerve Stimulation (TENS), it is intended to provide: ●symptomatic relief and management of chronic, intractable pain ●relief of pain associated with arthritis ●temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties	
Patient population	Adult	Not publicly available	/
OTC or prescription	OTC	OTC	Same
Basic unit specification			
Power supply	Adaptor Input: 100-240AC, 50-60Hz, 0.2A Output:5V, 1A Unit Input: 5V, 1A	Not publicly available	/
Leakage current	No earth leakage current	Not publicly available	/

Number of output modes	10	Not publicly available	/
Number of output channel	2	Not publicly available	/
Output intensity level	150	Not publicly available	/
-Synchronous or Alternating?	Synchronous	Not publicly available	/
Software/ Firmware/ Microprocessor Control?	Yes	Not publicly available	/
Automatic Overload trip	No	Not publicly available	/
Automatic no-load trip	No	Not publicly available	/
Patient override control method	On/Off button	Not publicly available	/
Indicator display -On/Off status -Low battery -Output mode -Time to cut-off	 Yes Yes Yes Yes	Not publicly available	/
Automatic Shut Off	Yes	Not publicly available	/
Dimensions (in mm)	330 (W) x 327 (H) x 92 (D)	Not publicly available	/
Weight	1.5Kg (Without accessories)	Not publicly available	/
Housing material and construction	ABS	Not publicly available	/
Compliance with voluntary standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 ISO10993-5 ISO10993-10	Not publicly available	/
Compliance with 21CFR 882 and 890	Yes	Not publicly available	/

Output specifications			
Waveform	Biphasic, Pulsed symmetric, rectangular wave	Not publicly available	/
Net Charge (per pulse)	0	Not publicly available	/
Maximum Phase Charge (@500Ω)	Footpads: 52.9μC Arthro-Kentro pads: 24.18μC TENS pads: 9.8μC	Not publicly available	/
Maximum Average Current(@500Ω)	Footpads: 8.31mA Arthro-Kentro pads: 4.67mA TENS pads: 6.85mA	Not publicly available	/
Maximum current density (@500Ω)	Footpads: 0.041mA/cm^2 Arthro-Kentro pads: 0.039mA/cm^2 TENS pads: 0.132mA/cm^2	Not publicly available	/
Maximum power density (@500Ω)	Footpads: 0.00017W/cm^2 Arthro-Kentro pads: 0.00009W/cm^2 TENS pads: 0.00045W/cm^2	Not publicly available	/
Pulse frequency	1Hz-100Hz (±5%)	Not publicly available	/
Pulse duration	TENS: 100-120μs EMS: 370-400μs and 950μs	Not publicly available	/

(9) 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 subject 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 and footpads. 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. The footpads have been tested for biocompatibility by reliable third-party lab. So we have reason to believe that the electrode patches are safe for the users. The electrode patches and foot pads 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

(10) Clinical information

Not applicable.

(11) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that subject device Transcutaneous Electrical Nerve Stimulator is as safe, as effective and performs as well as the legally marketed predicate device.