May 10, 2023

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: K222870
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator, Model: KTR-4031, KTR-4032, KTR-4012, KTR-4015, KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, KTR-4037, KTR-4039
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: September 19, 2022
Received: September 22, 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,

Pamela D. Scott -S

Pamela D. 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222870

Device Name
Transcutaneous Electrical Nerve Stimulator Model: KTR-4031, KTR-4032, KTR-4012, KTR-4015, KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, KTR-4037, KTR-4039.

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.**

# 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: | 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: | April 7, 2023 |

**(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-4031, KTR-4032, KTR-4012, KTR-4015, KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, KTR-4037, KTR-4039 |
| Common name: | Stimulator, Nerve, Transcutaneous, Over-The-Counter;<br>Stimulator, Muscle, Powered, For Muscle Conditioning;<br>Stimulator, Muscle, Powered;<br>Stimulator, Electrical, Transcutaneous, For Arthritis;<br>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** | SHENZHEN KENTRO MEDICAL ELECTRONICS CO., |

| | |
|---|---|
| | LTD |
| **Device Name and Model** | Transcutaneous Electrical Nerve Stimulator/ KTR-405 |
| **510(k) Number** | K220998 |
| **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 models KTR-4031, KTR-4032, KTR-4012, KTR-4015, KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, KTR-4037, KTR-4039 provide 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, mode 1-9 is for foot stimulation and mode body is for body stimulation; 2) wonderful electric pulse combination, 0~20 levels can be adjusted and chosen according to personal preference; 3) wireless remote control allows easy control of the device 5) use while seated or reclining; 6) LCD display makes the operation simple and easy.

Transcutaneous Electrical Nerve Stimulator is mainly composed of the main unit, remote control and electrode pads. Models KTR-4031, KTR-4032, KTR-4012, KTR-4015 are powered by 3*AA batteries, models KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, KTR-4037, KTR-4039 are powered by 3.7V rechargeable lithium battery. The remote control is powered by 2*AAA batteries. To start therapy, you need to install 3*AA batteries to the main unit and 2*AAA batteries to the remote control or ensure the lithium battery power is sufficient. 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 |
|---|---|---|---|
| Body electrode pads | EVA foam, carbon film, hydrogel, PET | Surface skin contact | Permanent (＞30d) |
| Foot pads (for models KTR-4012, KTR-4015, KTR-4021, KTR-4027, KTR-4029, KTR-4031, KTR-4032, KTR-4034, KTR-4036, KTR-4039) | Silica gel | Surface skin contact | Permanent (＞30d) |
| Foot pads (for models KTR-4026 and KTR-4037) | Stainless steel | Surface skin contact | Permanent (＞30d) |

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<br>Model: KTR-4031, KTR-4032, KTR-4012, KTR-4015, KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, KTR-4037, KTR-4039 | Transcutaneous Electrical Nerve Stimulator<br>Model: KTR-405 | / |
| 510 (k) number | Pending | K220998 | / |
| 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 | NUH, NGX, 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:<br>● 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<br>● to temporarily increase local blood circulation in healthy leg muscles<br>● to stimulate healthy muscles in order to improve and facilitate muscle performance<br>● 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 | 2) When using Electrical Muscle Stimulation, Transcutaneous Electrical Nerve Stimulator is intended:<br>● 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<br>● to temporarily increase local blood circulation in healthy leg muscles<br>● to stimulate healthy muscles in order to improve and facilitate muscle performance<br>● 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 | Same |

| | | | |
|---|---|---|---|
| | ● to relax muscle spasm<br>● to increase blood flow circulation<br>● for prevention of retardation of disuse atrophy<br>● for muscle re-education<br>● for maintaining or increasing range of motion<br>● Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis<br>● Provide quadricep strengthening<br>● Improve knee stability secondary to quadricep strengthening<br>2) When using Transcutaneous Electrical Nerve Stimulator to deliver Transcutaneous Electrical Nerve Stimulation (TENS), it is intended to provide:<br>● symptomatic relief and management of chronic, intractable pain<br>● relief of pain associated with arthritis<br>● 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 | ● to relax muscle spasm<br>● to increase blood flow circulation<br>● for prevention of retardation of disuse atrophy<br>● for muscle re-education<br>● for maintaining or increasing range of motion<br>● Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis<br>● Provide quadricep strengthening<br>● Improve knee stability secondary to quadricep strengthening<br>2) When using Transcutaneous Electrical Nerve Stimulator to deliver Transcutaneous Electrical Nerve Stimulation (TENS), it is intended to provide:<br>● symptomatic relief and management of chronic, intractable pain<br>● relief of pain associated with arthritis<br>● 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 | Adult | Same |
| OTC or prescription | OTC | OTC | Same |
| **Basic unit specification** | | | |
| Power supply | KTR-4031, KTR-4032, KTR-4012, KTR-4015 main unit: 4.5V DC 100mA or 3 AA batteries<br>KTR-4029, KTR-4027, KTR-4026, KTR-4021, KTR-4034, KTR-4036, | Adaptor Input: 100-240AC, 50-60Hz, 0.2A<br>Output:5V, 1A<br>Unit Input: 5V, 1A | Different |

| | | | |
|---|---|---|---|
| | KTR-4037, KTR-4039 main unit:<br>Input: 5V DC 1A<br>Battery Capacity: 3.7V DC 2200mAh Lithium battery<br>Remote control: 2 AAA batteries | | |
| Leakage current | No earth leakage current | No earth leakage current | Same |
| Number of output modes | 10 | 10 | Same |
| Number of output channel | 2 | 2 | Same |
| Output intensity level | 20 | 150 | Different |
| -Synchronous or Alternating? | Synchronous | Synchronous | Same |
| Software/ Firmware/ Microprocessor Control? | Yes | Yes | Same |
| Automatic Overload trip | No | No | Same |
| Automatic no-load trip | No | No | Same |
| Patient override control method | On/Off button | On/Off button | Same |
| Indicator display<br>-On/Off status<br>-Low battery<br>-Output mode<br>-Time to cut-off | Yes<br>Yes<br>Yes<br>Yes<br>Yes | Yes<br>Yes<br>Yes<br>Yes<br>Yes | Same |
| Automatic Shut Off | Yes | Yes | Same |
| Dimensions | KTR-4012, KTR-4015, KTR-4032, KTR-4034, KTR-4036, KTR-4037, KTR-4039: 350×350×68.5mm<br><br>KTR-4021, KTR-4026, KTR-4027, KTR-4029, KTR-4031: 365×365×68.5mm | 330 (W) x 327 (H) x 92 (D) mm | Different |
| Weight | About 1670g | 1.5Kg (Without accessories) | Different |

| | | | |
|---|---|---|---|
| Housing material and construction | ABS | ABS | Same |
| Compliance with voluntary standards | IEC 60601-1,<br>IEC 60601-1-2,<br>IEC 60601-2-10,<br>IEC 60601-1-11,<br>ISO10993-5;<br>ISO10993-10 | IEC 60601-1,<br>IEC 60601-1-2,<br>IEC 60601-2-10,<br>IEC 60601-1-11,<br>ISO10993-5;<br>ISO10993-10 | Same |
| Compliance with 21CFR 882 and 890 | Yes | Yes | Same |
| **Output specification** | | | |
| Waveform | Biphasic, Pulsed symmetric, rectangular wave | Biphasic, Pulsed symmetric, rectangular wave | Same |
| Net Charge (per pulse) | 0 | 0 | Same |
| Maximum Phase Charge (500Ω) | Footpads: 52.9μC @ 500Ω<br>TENS pads: 7.55μC@ 500Ω | Footpads: 52.9μC @ 500Ω<br>Arthro-Kentro pads: 24.18μC@ 500Ω<br>TENS pads: 9.8μC@ 500Ω | Similar |
| Maximum Average Current(500Ω) | Footpads: 8.42mA@ 500Ω<br>TENS pads: 5.95mA@ 500Ω | Footpads: 8.31mA@ 500Ω<br>Arthro-Kentro pads: 4.67mA@ 500Ω<br>TENS pads: 6.85mA@500Ω | Similar |
| Maximum current density (500Ω) | Footpads: 0.0395mA/ $cm^2$ and 0.0458mA/ $cm^2$<br>TENS pads: 0.198mA/ $cm^2$@ 500Ω | Footpads: 0.041mA/ $cm^2$@ 500Ω<br>Arthro-Kentro pads: 0.039mA/ $cm^2$@ 500Ω<br>TENS pads: 0.132mA/ $cm^2$@ 500Ω | Similar |
| Maximum power density (500Ω) | Footpads: 0.00017W/ $cm^2$ and 0.00019W/ $cm^2$<br>TENS pads: 0.00059W/ $cm^2$ @ 500Ω | Footpads: 0.00017W/ $cm^2$@ 500Ω<br>Arthro-Kentro pads: 0.00009W/ $cm^2$@ 500Ω<br>TENS pads: 0.00045W/ $cm^2$@ 500Ω | Similar |
| Pulse frequency | 1Hz-100Hz | 1Hz-100Hz (±5%) | Same |
| Pulse duration | TENS: 100-120μs<br>EMS: 370-400μs and 950μs | TENS: 100-120μs<br>EMS: 370-400μs and 950μs | Same |

**(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:

- ANSI AAMI ES 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 pads and foot pads. We have directly purchased the electrode pads from qualified supplier which has obtained FDA clearance with a 510(k) number of K171381 and been marketed to US market. The foot pads 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 pads and foot pads comply with the following standards.

- ISO 10993-5: 2009, Biological Evaluation of Medical Devices -- Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10: 2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-10: 2021, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization
- ISO 10993-23: 2021, Biological Evaluation of Medical Devices - Part 23: Tests for Irritation

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.

**(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.