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
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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
PRASstaff@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
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

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

<table>
<thead>
<tr>
<th>Component name</th>
<th>Material of Component</th>
<th>Body Contact Category</th>
<th>Contact Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrode patches</td>
<td>Hydrogel</td>
<td>Surface skin contact</td>
<td>Less than 24 hours</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Subject device (K170205)</th>
<th>Primary predicate device (K133929)</th>
<th>Trade name</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>Health</td>
<td>Expert</td>
<td>Low-Frequency</td>
<td>N/A</td>
</tr>
<tr>
<td>Therapy Instrument (Model: KTR-201, KTR-202, KTR-203)</td>
<td>Electronic Stimulator, Model: AST-300C and AST-300D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>----------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td><strong>Similar</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Regulation number</strong></td>
<td><strong>21 CFR 882.5890</strong></td>
<td><strong>Identical</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product code</strong></td>
<td><strong>NUH</strong></td>
<td><strong>NUH, NGX</strong></td>
<td><strong>Similar</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td><strong>II</strong></td>
<td><strong>II</strong></td>
<td><strong>Identical</strong></td>
<td></td>
</tr>
<tr>
<td><strong>OTC/Rx</strong></td>
<td><strong>OTC</strong></td>
<td><strong>OTC</strong></td>
<td><strong>Identical</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Basic unit specifications</strong></td>
<td><strong>Power supply</strong></td>
<td><strong>KTR-201: DC 3V, 30 mA</strong></td>
<td><strong>100-240VAC, 50-60Hz, 0.1A</strong></td>
<td><strong>Predicate is powered by mains supply but does not affect safety and effectiveness of subject device</strong></td>
</tr>
<tr>
<td></td>
<td><strong>KTR-202: DC 4.5V, 100 mA</strong></td>
<td><strong>KTR-203: DC 3V, 30mA</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Output modes</strong></td>
<td><strong>KTR-201: 10</strong></td>
<td><strong>25</strong></td>
<td><strong>Identical</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>KTR-202: 10</strong></td>
<td><strong>KTR-203: 5</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Output channels</strong></td>
<td><strong>KTR-201: 1</strong></td>
<td><strong>2</strong></td>
<td><strong>Similar. Does not affect safety and effectiveness of subject device.</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>KTR-202: 1</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>KTR-203: 2</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Software</strong></td>
<td><strong>Yes</strong></td>
<td><strong>Yes</strong></td>
<td><strong>Identical</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Automatic Shut off</strong></td>
<td><strong>Yes</strong></td>
<td><strong>Yes</strong></td>
<td><strong>Identical</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Timer range</strong></td>
<td><strong>15 mins</strong></td>
<td><strong>25 mins</strong></td>
<td><strong>Different but does not affect safety and effectiveness of subject device.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
<td><strong>KTR-201: 147mm x 59mm x 27.5mm</strong></td>
<td><strong>428mm x 428.8mm x 185mm</strong></td>
<td><strong>Not applicable</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100mm x 46mm</td>
<td>KTR-203: 98.9mm x 64mm x 31.25mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------</td>
<td>----------------------------------</td>
<td>----------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>KTR-201 (Host): 2.7oz</td>
<td>KTR-202 (Host): 5.7oz</td>
<td>KTR-203 (Host): 1.7oz</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70.5oz (2kg) (without accessories)</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Housing material and construction</strong></td>
<td>ABS</td>
<td>ABS</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td><strong>Compliance with voluntary standards</strong></td>
<td>IEC60601-1; IEC60601-1-2; IEC60601-1-11; IEC-60601-2-10</td>
<td>IEC60601-1; IEC60601-1-2; ISO10993-5; ISO10993-10</td>
<td>Similar</td>
<td></td>
</tr>
<tr>
<td><strong>Compliance with 21 CFR 898</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Identical</td>
<td></td>
</tr>
</tbody>
</table>

### Output specifications

<table>
<thead>
<tr>
<th>Waveform</th>
<th>Pulsed symmetric, biphasic, square wave</th>
<th>Pulse symmetric, biphasic, rectangular with interphase interval</th>
<th>Similar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum output voltage ($V_p$)</td>
<td>44V@500ohm 58V@2kohm 63.5V@10kohm</td>
<td>44V±10%@500ohm 80V±10%@2kohm 112V±10@10kohm</td>
<td>Similar</td>
</tr>
<tr>
<td>Maximum output current</td>
<td>88mA@500ohm 29mA@2kohm 6.35mA@10kohm</td>
<td>88mA±10%@500ohm 40mA±10%@2kohm 11.2mA+10%@10kohm</td>
<td>Similar</td>
</tr>
<tr>
<td>Net charge (per pulse)</td>
<td>0µC @500ohm</td>
<td>0µC @500ohm</td>
<td>Identical</td>
</tr>
<tr>
<td>Maximum phase charge</td>
<td>11.7µC @500ohm</td>
<td>12.78µC@500ohm</td>
<td>Similar</td>
</tr>
<tr>
<td>Maximum Average Current (500ohm)</td>
<td>7.4mA</td>
<td>0.968mA</td>
<td>Although the maximum average current is different, it is &lt;10mA, which complies with the requirements of IEC 60601-2-10, so the difference does not affect safety and effectiveness of the subject device.</td>
</tr>
<tr>
<td>Maximum current density</td>
<td>0.15mA/cm²@500ohm</td>
<td>0.235mA/cm²@500ohm</td>
<td>Current density is &lt;2mA/cm² which complies with the</td>
</tr>
</tbody>
</table>
requirements of IEC 60601-2-10, so the difference does not affect safety and effectiveness of the subject device.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Specification</th>
<th>Comparison</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum power density</td>
<td>0.56mW/cm² @ 500ohm</td>
<td>1.38mW/cm² @ 500ohm</td>
<td>Power density is &lt;0.25W/cm² and does not affect safety and effectiveness of the subject device</td>
</tr>
<tr>
<td>Pulse frequency</td>
<td>1-200Hz</td>
<td>77.3Hz</td>
<td>Similar</td>
</tr>
<tr>
<td>Pulse duration</td>
<td>50-220us</td>
<td>120us</td>
<td>Similar</td>
</tr>
<tr>
<td>ON time</td>
<td>No</td>
<td>0.6s</td>
<td>Does not affect safety and effectiveness of subject device</td>
</tr>
<tr>
<td>OFF time</td>
<td>No</td>
<td>0.6s</td>
<td>Does not affect safety and effectiveness of subject device</td>
</tr>
</tbody>
</table>

(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.