March 25, 2021

Shenzhen Kentro Medical Electronics Co., Ltd
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Room 2231, Building 1, Ruifeng center, Kaichuang road,
Huangpu district
Guangzhou, 51006 Cn

Re: K200177
Trade/Device Name: Low-frequency Multi-function physiotherapy instrument (Model: KTR-2240, KTR-2250, KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2610, KTR-2640, KTR-2650, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: December 21, 2020
Received: December 28, 2020

Dear Cassie Lee:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200177

Device Name
Low-frequency Multi-function physiotherapy instrument
(Model: KTR-2240, KTR-2250, KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2610, KTR-2640, KTR-2650, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652)

Indications for Use *(Describe)*
KTR-2240,KTR-2250,KTR-2610,KTR-2640,KTR-2650:（TENS, EMS, FITNESS）
TENS (Mode1~20): 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.
EMS (Mode 21~40): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.
FITNESS (Mode 41~50): Improvement of abdominal tone, strengthening of the abdominal muscle development of firmer abdomen.

KTR-2241,KTR-2251,KTR-2242,KTR-2252,KTR-2611,KTR-2641,KTR-2651,KTR-2612,KTR-2642,KTR-2652:
(TENS)
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.

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.

K Number: K200177

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- 510(k) Owner's Name: Shenzhen Kentro Medical Electronics Co., Ltd
- Establishment Registration Number: 3013671142
- Address: No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, ShenZhen, China
- Tel: +86-755-33825998
- Fax: +86-755-33825996
- Contact Person: Zewu Zhang (General Manger)
- Email: kentro@kentro.com.cn

2. Application Correspondent:

- Contact Person: Ms. Cassie Lee
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
- Tel: +86 20 8266 2446
- Email: regulatory@glomed-info.com

3. Subject Device Information

- Trade Name: Low-frequency Multi-function physiotherapy instrument
- Common Name: Stimulator, Muscle, Powered, For Muscle Conditioning; Stimulator, Nerve, Transcutaneous, Over-The-Counter
- Classification name: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief
- Review Panel: Neurology, Physical Medicine
- Product Code: NUH, NGX
- Regulation Class: II
- Regulation Number: 882.5890, 890.5850

4. Predicate Device Information

Sponsor	Shenzhen Kentro Medical Electronics Co., Ltd	Guangzhou Xinbo Electronic Co., Ltd.	Shenzhen OSTO Technology Co., Ltd.
Device Name and Model	KTR-2230, KTR-2220, KTR-2210, KTR-2231, KTR-2221, KTR-2211, KTR-2232, KTR-2222, KTR2212	Pain Therapy Device Models: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I	Intelligent Wireless Fitness Apparatus Models: AST-301, AST-302, AST-303
510(k) Number	K191982	K163611	K182136
Product Code	NUH, NGX	NUH, NGX, NYN	NGX

Regulation Number	882.5890, 890.5850	882.5890, 890.5850	890.5850
Regulation Class	II	II	II
Primary/ Reference device	Primary predicate device	Reference device	Reference device

5. Intended Use / Indications for Use

KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: (TENS, EMS, FITNESS)
TENS (Mode 1~20): 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.
EMS (Mode 21~40): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.
FITNESS (Mode 41~50): Improvement of abdominal tone, strengthening of the abdominal muscle development of firmer abdomen.

KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: (TENS)
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.

6. Device Description

The Low-frequency Multi-function physiotherapy instrument is a portable and battery powered multifunctional device. The low-frequency multi-function physiotherapy instrument (models: KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650) offering Transcutaneous Electronic Nerve Stimulator (TENS), Electronic Muscle Stimulator (EMS) stimulation. It has 50 operation modes, which can give certain electrical pulse through electrode pads placed on the skin to help users to enjoy body stimulation. And the TENS (Mode 1~20) is 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. EMS (Mode 21~40) is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. FITNESS (Mode 41~50) is indicated for the improvement of abdominal muscle tone, for the strengthening of the abdominal muscles and for the development of a firmer abdomen.

The low-frequency multi-function physiotherapy instrument (models: KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652) offering Transcutaneous Electronic Nerve Stimulator (TENS). It has 15 operation modes, 9 Manual mode, and 6 automatic mode, which can give certain electrical pulse through electrode pads placed on the skin to help users to enjoy body stimulation. The TENS (Mode 1-15) is intended 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.

The electronic stimulatory module has the operating elements of ON/OFF Key, Display screen, Mode Selection key and Intensity Modification keys.

The LCD display screen can show selected mode and program, output intensity, stimulate frequency, and time remaining of an application mode.
The device is equipped with accessories of electrode pads, electrode wires, and batteries. The electrode wire is used to connect the patches to the main unit.
The electrode pads are complying with the biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization), are interchangeable.

7. Test Summary

Low-frequency Multi-function physiotherapy instrument has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Usability test according to IEC 62366-1 standard
- 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 body-contacting components of this device are electrode patches. We have directly purchased the electrode patches from qualified supplier (Shenzhen Quality Medical Technology Co., Ltd.) 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: 2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Low-frequency Multi-function physiotherapy instrument is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
Device Name and Model	Low-frequency Multi-function physiotherapy instrument Model: KTR-2240, KTR-2250, KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2610, KTR-2640, KTR-2650, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652	Low-frequency Multi-function physiotherapy instrument Model: KTR-2230, KTR-2220, KTR-2210, KTR-2231, KTR-2221, KTR-2211, KTR-2232, KTR-2222, KTR-2212	Pain Therapy Device, Models: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I	Intelligent Wireless Fitness Apparatus Models: AST-301, AST-302, AST-303	--
510(k) Number	K200177	K191982	K163611	K182136	--
Product code	NUH, NGX	NUH, NGX	NUH, NYN, NGX	NGX	SE
Intended Use	KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: (TENS, EMS, FITNESS) TENS (Mode 1~20): 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. EMS (Mode 21~40): It is intended to stimulate healthy muscles in order to improve and	KTR-2210, KTR-2220, KTR-2230: (TENS, EMS, FITNESS) TENS (Mode 1~20): 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. EMS (Mode 21~40): It is intended to stimulate healthy	To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower back, back of the neck, upper extremities (shoulder and arm), lower extremities (leg and feet) due to strain from exercise or normal household work activities by applying current to stimulate nerve. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain	Intelligent Wireless Fitness Apparatus is indicated to be used for: Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen. Strengthening, toning and firming of buttocks and thighs.	SE

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
	facilitate muscle performance. FITNESS (Mode 41~50): Improvement of abdominal tone, strengthening of the abdominal muscle development of firmer abdomen. KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: (TENS) 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.	muscles in order to improve and facilitate muscle performance. FITNESS (Mode 41~50): Improvement of abdominal tone, strengthening of the abdominal muscles development of firmer abdomen. KTR-2211, KTR-2221, KTR-2231, KTR-2212, KTR-2222, KTR-2232: (TENS) 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.	associated with arthritis (Choose Mode B or C). To stimulate healthy muscles in order to improve and facilitate muscle performance (Choose Mode A). To temporarily increase local blood.		
Power Source(s)	For model KTR-2240, KTR-2250, KTR-2241, KTR-2251, KTR-2242, KTR-2252: DC 4.5V (3xAAA LR03 battery), 180mA For model KTR-2610,	DC 4.5V (3*AAA LR03 battery), 180mA	DC 3.0V, 2 x AAA	Adapter (Model HDMU05E-050100, HDMU05B-050100, HDMU05U-050100) Input: 100-240 Vac; 50/60 Hz; 0,3A; Output: 5 V; 1A	SE

Elements of Comparison		Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
		KTR-2640, KTR-2650, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: 3.7V/250mAh lithium battery			Rechargeable Lithium-ion Battery: 3.7Vdc	
-Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	DC: 0.5μA	DC: 0.5μA	DC: 0.5μA	< 0.01μA	SE
	SFC	DC: 0.6μA	DC: 0.6μA	DC: 0.6μA	0.1mA	
Average DC current through electrodes when device is on but no pulses are being applied		< 0.01μA	< 0.01μA	< 0.01	Not publicly available	SE
Number of Output Channels:		2 channels	2 channels	2 Channels: for models P.T.S-II, P.T.S-IIA, P.T.S-IIB; 1 Channel: for model CP-I	2	SE
Number of Output Modes		For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: 50 modes; For model KTR-2241,	50	3	8	SE

Elements of Comparison		Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
		KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: 15 modes				
Output Intensity Level		16 steps	16 steps	5 steps	Not publicly available	SE
Synchronous or Alternating?		Synchronous	Synchronous	Synchronous	Alternating	SE
Method of Channel Isolation		Voltage Transform Isolation “Ch1+” and “Ch1-” buttons for channel 1, “Ch2+” and “Ch2-” buttons for channel 2	Voltage Transform Isolation “Ch1+” and “Ch1-” buttons for channel 1, “Ch2+” and “Ch2-” buttons for channel 2	Parallel connection	Voltage Transform Isolation	SE
Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Regulated Voltage	Voltage Control	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	Yes	SE
Automatic Overload Trip		No	No	No	No	SE
Automatic No-Load Trip		No	No	No	No	SE
Automatic Shut Off		Yes	Yes	Yes	Yes	SE
User Override Control		Yes	Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	Yes	SE
	Low Battery	Yes	No	No	Yes	SE
	Voltage/ Current Level	Yes	Yes	Yes	Yes	SE
Timer Range		15, 30, 45min	15, 30, 45min	10, 20, 40 min	15 min	SE
Weight		For model KTR-2240, KTR-2241, KTR-2242: 110g For model KTR-2250,	KTR-2210, KTR-2211, KTR-2212: 76g KTR-2220, KTR-2221, KTR-2222: 82g	Main Unit: P.T.S-II: 75g P.T.S-IIA: 100g P.T.S-IIB: 100g	80g (Without accessories)	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
	KTR-2251, KTR-2252: 114g For model KTR-2610, KTR-2611, KTR-2612: 70g For model KTR-2640, KTR-2641, KTR-2642: 68g For model KTR-2650, KTR-2651, KTR-2652: 71g	KTR-2230, KTR-2231, KTR-2232: 75g Electrode :12g Electrode wire: 12g	CP-I: 66g Electrode: Big Patch Electrode: 40g Small Patch Electrode:10g Insole Electrode: 200g Sole Plant Electrode A (only for CP-I): 900g Sole Plant Electrode B: 920g		
Dimensions	Main unit: For model KTR-2240, For model KTR-2240, KTR-2241, KTR-2242: 122mm x 55mm x 21mm; For model KTR-2250, KTR-2251, KTR-2252: 122mm x 55mm x 21.6mm; For model KTR-2610, KTR-2611, KTR-2612: 122mm x 55mm x 15.7mm; For model KTR-2640, KTR-2641, KTR-2642: 122mm x 55mm x 14.9mm; For model KTR-2650, KTR-2651, KTR-2652: 122mm x 55mm x 15.5mm Electrode Pads: 3 kinds	Main unit: KTR 2210, KTR-2211, KTR-2212: 122mm * 55mm * 21.8mm; KTR-2220, KTR-2221, KTR-2222, KTR-2230, KTR-2231 and KTR- 2232: 120mm * 55mm * 20.4mm Electrode: Square shape: 50mm x 50mm (Area: 25cm^2) Irregularly shape: about 50mm x 70mm (Area: about 30cm^2)	Main Unit: P.T.S-II: 110 x 78 x 20 mm P.T.S-IIA: 135 x 82 x 20 mm P.T.S-IIB: 135 x 82 x 20 mm CP-I: 92 x 78 x 20 mm Electrode: Large Patch Electrode: 120 x 80 mm Small Patch Electrode: 46 x 46 mm Insole Electrode: 260 x 110 mm Sole Plant Electrode A (only for CP-I): 450 x 450 x 90 mm Sole Plant Electrode B: 450 x 450 x 90 mm	Main Unit: 50X37mm Electrode pad for model AST-301: 198mm x 164mm x 2mm Electrode pad for model AST-302: 192mm x 164mm x 2mm Electrode pad for model AST-303: 125 mm x 80mm x 2mm Each gel sheet 90mm x 60mm x2 mm	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
	EPAD-D01: 70×52mm EPAD-D02: 50×50mm EPAD-D03: 50×50mm				
Housing Materials and Construction	Main unit: ABS plastic	Main unit: ABS plastic	Main unit: ABS plastic	Main unit: ABS plastic	SE
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Symmetrical, Biphasic	SE
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular, with interphase interval	SE
Maximum Output Voltage	46.0V±10% @ 500Ω	55V±10% @ 500Ω	40V±10% @ 500Ω	44V±10% @ 500Ω	SE Note 2*
	57.5V±10% @ 2KΩ	75V±10% @ 2KΩ	80V±10% @ 2KΩ	80V±10% @ 2KΩ	
	66.5V±10% @ 10KΩ	85V±10% @ 10KΩ	95V±10% @ 10KΩ	112V±20% @ 10KΩ	
Maximum Output Current	92mA±10% @ 500Ω	110mA±10% @ 500Ω	80mA±10%@ 500Ω	88mA±10% @ 500Ω	SE Note 2*
	28.8mA±10% @ 2KΩ	37.5mA±10% @ 2KΩ	40mA±10% @ 2KΩ	40mA±10% @ 2KΩ	
	6.65mA±10% @ 10KΩ	8.5mA±10%@10KΩ	9.5mA±10%@10Ω	11.2mA±10%@10KΩ	
Pulse Duration	TENS: 120μs, EMS: 200μs, FITNESS: 200μs	TENS: 120μs, EMS: 200μs, FITNESS: 200μs	200μs	120μs	SE
Pulse frequency	TENS:(20-100) Hz, EMS:(1-15) Hz, FITNESS:(2-16) Hz	TENS:(20-100) Hz, EMS:(1-15) Hz, FITNESS:(2-16) Hz	13.7~48.5Hz	8.33Hz	SE
Net Charge (per pulse)	0μC @ 500Ω, Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω, Method: Balanced waveform	10.56μC @ 500Ω	SE
Maximum Phase Charge	18.40μC @ 500Ω	15.97 μC @ 500Ω,	19.2μC @ 500Ω	12.78μC @ 500Ω	SE Note 2*
Maximum Average Current	3.20mA	1.60mA	1.53mA @ 500Ω	1.69mA @ 500Ω	SE Note 2*

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
Maximum Average Power Density	0.204mW/cm²@500Ω	0.08mW/cm²	0.056mW/cm² @500Ω	15.37μW/cm² @500Ω	SE Note 2*
Maximum Average Current Density	0.1279mA/cm²@ 500Ω	0.064mA/cm² @ 500Ω	0.073mA/cm²@500Ω	0.26 mA/cm² @500Ω	SE Note 2*
ON Time	0.6s	0.6s	2s	3s	SE
OFF Time	0.6s	0.6s	2s	3s	SE
Environment for operating	Environment temperature: +5°C-+40°C; Environment humidity: 15%-93%RH; Atmospheric environment conditions: 700hPa-1060hPa	Environment temperature: +5°C-+40°C; Environment humidity: 15%-93%RH; Atmospheric environment conditions: 700hPa-1060hPa	Temperature: 5~40°C, Humidity: ≤80%RH, Atmospheric Pressure: 86~106kPa	0°C to +40°C	SE
Environment for storage	Environment temperature: 0°C-+55°C; Environment humidity: 0-93%RH; Atmospheric environment conditions: 700hPa-1060hPa.	Environment temperature: -25°C-+70°C; Environment humidity: 0-93%RH; Atmospheric environment conditions: 700hPa-1060hPa.	Temperature: Main Unit: -20~55°C, Electrode Pad: 10~20°C Humidity: 10~95% RH Atmospheric Pressure: 50~106 kPa	Not publicly available	SE
Biocompatibility	All user directly contacting materials are compliance with ISO 10993-5 and ISO 10993-10 requirements.	All user directly contacting materials are compliance with ISO 10993-5 and ISO 10993-10 requirements.	All user directly contacting materials are compliance with ISO 10993-5 and ISO 10993-10 requirements.	All user directly contacting materials are compliance with ISO 10993-5 and ISO 10993-10 requirements.	SE
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and 60601-2-10	SE

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference Device)	Predicate Device 3 (Reference Device)	Remark
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

**More detail information please refer to the Supplement SE table for all modes output specifications*

Supplement SE table for all modes output specifications					
	Subject device	**Predicate device 1 (K191982)**	**Reference device 2 (K163611)**	**Reference device 3 (K182136)**	**Remark**
Pulse Duration	TENS: 120μs, EMS: 200μs, FITNESS: 200μs	TENS: 120μs, EMS: 200μs, FITNESS: 200μs	200μs	120μs	SE
Pulse frequency	TENS:(20-100) Hz, EMS:(1-15) Hz, FITNESS:(2-16) Hz	TENS:(20-100) Hz, EMS:(1-15) Hz, FITNESS:(2-16) Hz	13.7~48.5Hz	8.33Hz	SE Note 2
Maximum Output Voltage ±10% @ 500Ω	For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: Mode 1: 41.3V Mode 2: 40.0V Mode 3: 42.4V Mode 4: 43.0V Mode 5: 41.6V Mode 6: 38.4V Mode 7: 40.3V Mode 8: 38.4V Mode 9: 38.0V Mode 10: 39.6V Mode 11: 37.8V Mode 12: 37.4V Mode 13: 36.2V Mode 14: 27.2V Mode 15: 38.2V Mode 16: 38.2V Mode 17: 37.2V Mode 18: 37.4V Mode 19: 27.3V Mode 20: 22.2V Mode 21: 40.4V Mode 22: 46.0V Mode 23: 41.2V Mode 24: 41.0V Mode 25: 41.2V Mode 26: 40.4V Mode 27: 40.0V Mode 28: 40.8V	55V±10%	40V±10%	44V±10%	SE Note 2

	Mode 29: 39.5V Mode 30: 39.6V Mode 31: 21.6V Mode 32: 21.8V Mode 33: 21.6V Mode 34: 21.2V Mode 35: 21.2V Mode 36: 21.6V Mode 37: 21.6V Mode 38: 21.6V Mode 39: 20.0V Mode 40: 20.8V Mode 41: 39.3V Mode 42: 39.5V Mode 43: 38.2V Mode 44: 38.2V Mode 45: 37.6V Mode 46: 37.5V Mode 47: 37.8V Mode 48: 37.6V Mode 49: 37.6V Mode 50: 37.8V For model KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: Mode 1: 41.3V Mode 2: 40.0V Mode 3: 42.4V Mode 4: 43.0V Mode 5: 41.6V Mode 6: 38.4V Mode 7: 40.3V Mode 8: 37.8V Mode 9: 36.2V Mode 10: 40.3V Mode 11: 41.3V Mode 12: 43.0V Mode 13: 41.6V Mode 14: 40.3V Mode 15: 37.8V				
Maximum Output Current ±10% @ 500Ω	For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: Mode 1: 82.6mA Mode 2: 80.0mA Mode 3: 84.8mA Mode 4: 86.0mA Mode 5: 83.2mA Mode 6: 76.8mA Mode 7: 80.6mA Mode 8: 76.8mA Mode 9: 76.0mA Mode 10: 79.2mA Mode 11: 75.6mA Mode 12: 74.8mA Mode 13: 27.4mA Mode 14: 54.4mA Mode 15: 76.4mA Mode 16: 76.4mA Mode 17: 74.4mA Mode 18: 74.8mA Mode 19: 54.6mA Mode 20: 44.4mA Mode 21: 80.8mA Mode 22: 92.0mA Mode 23: 82.4mA Mode 24: 82.0mA Mode 25: 82.4mA Mode 26: 80.8mA	110mA±10% @ 500Ω	80mA±10%@ 500Ω	88mA±10% @ 500Ω	SE Note 2

	Mode 27: 80.0mA Mode 28: 81.6mA Mode 29: 79.0mA Mode 30: 79.2mA Mode 31: 43.2mA Mode 32: 43.6mA Mode 33: 43.2mA Mode 34: 42.4mA Mode 35: 42.4mA Mode 36: 43.2mA Mode 37: 43.2mA Mode 38: 43.2mA Mode 39: 40.0mA Mode 40: 41.6mA Mode 41: 78.9mA Mode 42: 79.0mA Mode 43: 76.4mA Mode 44: 76.4mA Mode 45: 75.2mA Mode 46: 75.0mA Mode 47: 75.6mA Mode 48: 75.2mA Mode 49: 75.2mA Mode 50: 75.6mA For model KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: Mode 1: 82.6mA Mode 2: 80.0mA Mode 3: 84.8mA Mode 4: 86.0mA Mode 5: 83.2mA Mode 6: 76.8mA Mode 7: 80.6mA Mode 8: 75.6mA Mode 9: 72.4mA Mode 10: 80.6mA Mode 11: 82.6mA Mode 12: 86mA Mode 13: 83.2mA Mode 14: 80.6mA Mode 15: 75.6mA				
Maximum Phase Charge µC@ 500Ω	For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: Mode 1: 9.91µC Mode 2: 9.60µC Mode 3: 10.18µC Mode 4: 10.32µC Mode 5: 9.98µC Mode 6: 9.22µC Mode 7: 9.67µC Mode 8: 9.22µC Mode 9: 9.124µC Mode 10: 9.50µC Mode 11: 9.07µC Mode 12: 8.98µC Mode 13: 8.69µC Mode 14: 6.53µC Mode 15: 9.170µC Mode 16: 9.17µC Mode 17: 8.93µC Mode 18: 8.98µC Mode 19: 6.55µC Mode 20: 5.33µC Mode 21: 16.16µC Mode 22: 18.40µC Mode 23: 16.48µC Mode 24: 16.40µC	15.97µC @ 500Ω	19.2µC @ 500Ω	12.78µC @ 500Ω	SE Note 2

	Mode 25: 16.48µC Mode 26: 16.16µC Mode 27: 16.00µC Mode 28:16.32µC Mode 29: 15.80µC Mode 30: 15.84µC Mode 31: 8.64µC Mode 32: 8.726µC Mode 33: 8.64µC Mode 34: 8.48µC Mode 35: 8.48µC Mode 36: 8.64µC Mode 37: 8.64µC Mode 38: 8.64µC Mode 39: 8.00µC Mode 40: 8.32µC Mode 41: 15.72µC Mode 42: 15.80µC Mode 43: 15.28µC Mode 44: 15.28µC Mode 45: 15.04µC Mode 46: 15.00µC Mode 47: 15.12µC Mode 48: 15.04µC Mode 49: 15.04µC Mode 50: 15.12µC For model KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: Mode 1: 9.91µC Mode 2: 9.60µC Mode 3: 10.18µC Mode 4: 10.32µC Mode 5: 9.98µC Mode 6: 9.22µC Mode 7: 9.67µC Mode 8: 9.07µC Mode 9: 8.69µC Mode 10: 9.67µC Mode 11: 9.91µC Mode 12: 10.32µC Mode 13: 9.98µC Mode 14: 9.67µC Mode 15: 9.07µC				
Maximum Average Current@ 500Ω	For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: Mode 1: 0.40mA Mode 2: 0.48mA Mode 3: 0.61mA Mode 4: 0.83mA Mode 5: 1.00mA Mode 6: 1.11mA Mode 7: 1.93mA Mode 8: 0.74mA Mode 9: 0.91mA Mode 10: 1.14mA Mode 11: 1.45mA Mode 12: 1.80mA	1.60mA	1.53mA @ 500Ω	1.69mA @ 500Ω	SE Note 2

	Mode 13: 2.08mA Mode 14: 2.61mA Mode 15: 1.10mA Mode 16: 1.38mA Mode 17: 1.61mA Mode 18: 2.15mA Mode 19: 2.36 mA Mode 20: 3.20mA Mode 21: 0.10mA Mode 22: 0.22mA Mode 23: 0.30mA Mode 24: 0.49mA Mode 25: 0.59mA Mode 26: 0.68mA Mode 27: 0.86mA Mode 28:0.98mA Mode 29: 1.14mA Mode 30: 1.43mA Mode 31: 0.03mA Mode 32: 0.05mA Mode 33: 0.08mA Mode 34: 0.13mA Mode 35: 0.15mA Mode 36: 0.18mA Mode 37: 0.23mA Mode 38: 0.26mA Mode 39: 0.29mA Mode 40: 0.37mA Mode 41: 0.06mA Mode 42: 0.09mA Mode 43: 0.15mA Mode 44: 0.21mA Mode 45: 0.24mA Mode 46: 0.27mA Mode 47: 0.30mA Mode 48: 0.33mA Mode 49: 0.39mA Mode 50: 0.48mA For model KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: Mode 1: 0.40mA Mode 2: 0.48mA Mode 3: 0.61mA Mode 4: 0.83mA Mode 5: 1.00mA Mode 6: 1.11mA Mode 7: 1.93mA Mode 8: 1.45mA Mode 9: 2.08mA Mode 10: 1.93mA Mode 11: 0.40mA Mode 12: 0.83mA Mode 13: 1.00mA Mode 14: 1.93mA Mode 15: 1.45mA				

Maximum Average Power Density mW/cm²@ 500Ω	For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: Mode 1: 0.0031 Mode 2: 0.0046 Mode 3: 0.0074 Mode 4: 0.0136 Mode 5: 0.0199 Mode 6: 0.0244 Mode 7: 0.0748 Mode 8: 0.0108 Mode 9: 0.0166 Mode 10: 0.0260 Mode 11: 0.0421 Mode 12: 0.0644 Mode 13: 0.0869 Mode 14: 0.1363 Mode 15: 0.0242 Mode 16: 0.0378 Mode 17: 0.0516 Mode 18: 0.0928 Mode 19: 0.1112 Mode 20: 0.2044 Mode 21: 0.0002 Mode 22: 0.0009 Mode 23: 0.0017 Mode 24: 0.0048 Mode 25: 0.0070 Mode 26: 0.0092 Mode 27: 0.0149 Mode 28: 0.0192 Mode 29: 0.0259 Mode 30: 0.0406 Mode 31: 0.0001 Mode 32: 0.0001 Mode 33: 0.0001 Mode 34: 0.0003 Mode 35: 0.0005 Mode 36: 0.0007 Mode 37: 0.0011 Mode 38: 0.0013 Mode 39: 0.0017 Mode 40: 0.0028 Mode 41: 0.0001 Mode 42: 0.0002 Mode 43: 0.0005 Mode 44: 0.0009 Mode 45: 0.0012 Mode 46: 0.0015 Mode 47: 0.0018 Mode 48: 0.0022 Mode 49: 0.0031 Mode 50: 0.0047 For model KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: Mode 1: 0.0031 Mode 2: 0.0046 Mode 3: 0.0075 Mode 4: 0.0136 Mode 5: 0.0199 Mode 6: 0.0245 Mode 7: 0.0748 Mode 8: 0.0421 Mode 9: 0.0869 Mode 10: 0.0748 Mode 11: 0.0031 Mode 12: 0.0136 Mode 13: 0.0199 Mode 14: 0.0745 Mode 15: 0.0421	0.08mW/cm² @ 500Ω	0.056m W/cm² @500Ω	Not publicly available	SE Note 2

Maximum Average Current Density mA/cm²@ 500Ω	For model KTR-2240, KTR-2250, KTR-2610, KTR-2640, KTR-2650: Mode 1: 0.0159 Mode 2: 0.0192 Mode 3: 0.0244 Mode 4: 0.0330 Mode 5: 0.0399 Mode 6: 0.0442 Mode 7: 0.0774 Mode 8: 0.0295 Mode 9: 0.0365 Mode 10: 0.0456 Mode 11: 0.0581 Mode 12: 0.0718 Mode 13: 0.0834 Mode 14: 0.1044 Mode 15: 0.0440 Mode 16: 0.0550 Mode 17: 0.0643 Mode 18: 0.0862 Mode 19: 0.0943 Mode 20: 0.1279 Mode 21: 0.0039 Mode 22: 0.0088 Mode 23: 0.0119 Mode 24: 0.0197 Mode 25: 0.0237 Mode 26: 0.0271 Mode 27: 0.0346 Mode 28: 0.0392 Mode 29: 0.0455 Mode 30: 0.0570 Mode 31: 0.0010 Mode 32: 0.0021 Mode 33: 0.0031 Mode 34: 0.0051 Mode 35: 0.0061 Mode 36: 0.0073 Mode 37: 0.0093 Mode 38: 0.0104 Mode 39: 0.0115 Mode 40: 0.0150 Mode 41: 0.0025 Mode 42: 0.0038 Mode 43: 0.0061 Mode 44: 0.0086 Mode 45: 0.0096 Mode 46: 0.0108 Mode 47: 0.0121 Mode 48: 0.0132 Mode 49: 0.0156 Mode 50: 0.0194 For model KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652: Mode 1: 0.0159 Mode 2: 0.0192 Mode 3: 0.0224 Mode 4: 0.0330 Mode 5: 0.0399 Mode 6: 0.0442 Mode 7: 0.0774 Mode 8: 0.0581 Mode 9: 0.0834 Mode 10: 0.0774 Mode 11: 0.0159 Mode 12: 0.0330 Mode 13: 0.0399 Mode 14: 0.0774 Mode 15: 0.0581	0.064mA/cm²@500Ω	0.073mA/cm²@500Ω	0.026 mA/cm² @500Ω	SE Note 2

Comparison in Detail(s):
Note 1:
Although the “Weight” and “Dimensions” are a little different from the predicate device, but these are not critical parameter for effectiveness, but they all met the requirements of the same standard as 60601-1, 60601-1-11 and 60601-1-2. So, the differences between the subject device and predicate devices will not raise any safety or effectiveness.

Note 2:
Although the “Maximum Output Voltage”, “Maximum Output Current”, "Maximum Phase Charge", “Maximum Average Current”, “Maximum Current Density (r.m.s)”, “Maximum Average Power Density” and “Maximum Average Current Density” are a little different from the predicate devices, but they all meet the requirements of the same standards as IEC 60601-1 and IEC 60601-2-10. So, the differences between the subject device and predicate devices will not raise any safety or effectiveness.

Finial Conclusion:
The conclusion drawn from the nonclinical tests demonstrate that the subject devices Low-frequency Multi-function physiotherapy instrument (Model: KTR-2240, KTR-2250, KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2610, KTR-2640, KTR-2650, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652) as safe, as effective as well as the legally marketed device identified in K191982, K163611 and K182136.

9. Date of the summary prepared: March 3, 2021