October 19, 2020

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, Guangdong 51006
China

Re: K200237
Trade/Device Name: Transcutaneous Electronic Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 15, 2020
Received: July 21, 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, MS.
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)*
K200237

Device Name
(Model: KTR-2401, KTR-2402, KTR-2411,KTR-2412, KTR-2301, KTR-2302, KTR-2341, KTR-2342, KTR-2491, KTR-2492, KTR-2493, KTR-2494)

Indications for Use *(Describe)*
Transcutaneous Electronic Nerve Stimulator is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 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.3, Xihu industry zone, Xikeng Village, Henggang Town, Longgang District, Shenzhen, Guangdong, China
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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: Transcutaneous Electronic Nerve Stimulator
- Model: KTR-2401, KTR-2402, KTR-2411, KTR-2412, KTR-2301, KTR-2302, KTR-2341, KTR-2342, KTR-2491, KTR-2492, KTR-2493, KTR-2494
- Common Name: Electronic Stimulator
- Classification name: Stimulator, Nerve, Transcutaneous, Muscle, Powered, For Muscle Conditioning, Over-The-Counter
- Review Panel: Neurology, Physical Medicine
- Product Code: NUH
- Regulation Class: II
- Regulation Number: 890.5850

4. Predicate Device Information

Sponsor	M.I.TECH Co., Ltd.	Shenzhen Kentro Medical Electronics Co., Ltd	Guangzhou Xinbo Electronic Co., Ltd.
Device Name and Model	HANAROCare ReJu	Transcutaneous Electrical Nerve Stimulator Model:KTR-206, KTR-208, KTR-209	Pain Therapy Device Model: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I

510(k) Number	K160893 (Primary)	K183288	K163611
Product Code	NUH	NUH, NGX, NYN	NUH, NGX, NYN
Regulation Number	882.5890	882.5890	882.5890
Regulation Class	II	II	II

5. Device Description

Transcutaneous Electronic Nerve Stimulator (Models:
KTR-2401, KTR-2402, KTR-2411, KTR-2412, KTR-2301, KTR-2302, KTR-2341, KTR-2342, KTR-2491, KTR-2492, KTR-2493, KTR-2494) is a portable and battery powered multifunctional device, offering Transcutaneous Electronic Nerve Stimulator. They can give certain electrical pulse through electrode pads placed on the skin to help users to enjoy body stimulation.
For models: KTR-2401, KTR-2402, KTR-2411, KTR-2412, KTR-2301, KTR-2302, KTR-2341, KTR-2342 have 3 operation modes;
For models: KTR-2491, KTR-2492, KTR-2493, KTR-2494 have 15 operation modes, 9 manual mode, and 6 automatic mode. They can be remotely controlled with an accessory remote control. And there is a LCD displays on remote control, which display mode and treatment time.

The electronic stimulator module has unified the operating elements of ON/OFF button, Intensity adjust button and Mode selection button.
The device is equipped with accessories of electrode pads, batteries and remote control (For KTR-249X series).
The electrode pads are complying with the biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization), are interchangeable.

6. Intended Use / Indications for Use

Transcutaneous Electronic Nerve Stimulator is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

7. Test Summary

Transcutaneous Electronic Nerve Stimulator 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
- Biocompatibility test according to ISO 10993-1, ISO 10993-5 and ISO 10993-10 standards
- 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 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 and Guidance for Powered Muscle Stimulator for Muscle Conditioning

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Transcutaneous Electronic Nerve Stimulator is substantially equivalent to the primary predicate device quoted above.

The differences between the subject device and primary predicate device do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device 1 (primary)**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
Device Name and Model	Transcutaneous Electronic Nerve Stimulator Model: KTR-2401,KTR-2402,KTR-2411,KTR-2412,KTR-2301,KTR-2302,KTR-2341,KTR-2342,KTR-2491,KTR-2492,KTR-2493,KTR-2494	HANAROCare ReJu	Transcutaneous Electrical Nerve Stimulator Model: KTR-206, KTR-208, KTR-209	Pain Therapy Device, Models: P.T.S-II, P.T.S-IIA, P.T.S-IIB, CP-I	--
510(k) Number	Applying	K160893	K183288	K163611	--
Product code	NUH	NUH	NUH, NGX, NYN	NUH, NGX, NYN	SE
Intended Use	Transcutaneous Electronic Nerve Stimulator is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	HANAROCare ReJu is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, arm, leg, foot, due to strain from exercise or normal household and work activities.	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	SE

Elements of Comparison		**Subject Device**	**Predicate Device 1 (primary)**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
					chronic, intractable pain and relief of pain 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 KTR-23XX series: CR2032; 3Vdc; 240mAh	Lithium-polymer, 3.7V	KTR-206: 2 AAA batteries (DC3V)	DC 3.0V, 2 x AAA	SE Note 1
		For KTR-24XX series: PL301526; 3.7Vdc, 250mAh		KTR-208: 2 AAA batteries (DC 3V)		
				KTR-209: AAA LR03 battery ×3(DC 4.5V)		
Patient Leakage Current	NC	DC: 0.5μA	DC: 0.5μA	N/A (Battery operated)	DC: 0.5μA	SE
	SFC	DC: 0.6μA	DC: 0.6μA		DC: 0.6μA	
Average DC current through electrodes when device is on but no pulses are being applied		< 0.01μA	< 0.01μA	--	< 0.01μA	SE
Number of Output Channels:		1 channel	1 channel	2 channels	2 channels	SE
Number of Output Modes		For KTR-23XX series: 3 modes	4	5	3	SE Note 2
		For KTR-240X series				

Elements of Comparison		**Subject Device**	**Predicate Device 1 (primary)**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
		& KTR-241X series: 3 modes For KTR-249X series: 15 modes				
Output Intensity Level		16 steps	15steps	16 steps	5 steps	SE
Synchronous or Alternating?		Synchronous	Unknown	Synchronous	Synchronous	SE
Regulated Current or Regulated Voltage?		Voltage Control	Unknown	Voltage Control	Voltage Control	SE
Software/ Firmware/ Microprocessor Control?		Yes	Yes	Yes	Yes	SE
Automatic Overload Trip		No	Unknown	No	No	SE
Automatic No-Load Trip		No	Unknown	No	No	SE
Automatic Shut Off		Yes	Unknown	Yes	Yes	SE
User Override Control		Yes	Unknown	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Unknown	Yes	Yes	SE
	Low Battery	No	Unknown	No	No	SE
	Voltage/ Current Level	Yes	Unknown	Yes	Yes	SE

Elements of Comparison	**Subject Device**	**Predicate Device 1 (primary)**	**Predicate Device 2**	**Predicate Device 3**	**Remark**
Timer Range	15min	20 minutes fixed	25min15min default KTR-206:5/10/15min KTR-208:5/10/15/20/25/30 min KTR-209:5/10/15/20/25/30 min	10, 20, 40 min	SE
Weight	Main Unit:31g Electrode: EPAD-H01: 13g, EPAD-H02: 13g, EPAD-F01:15g, EPAD-F02: 10g, EPAD-F03: 12g, EPAD-B01: 8g, EPAD-T01: 8g, EPAD-Z01: 55g	11g	KTR-206: 1.68oz KTR-208: 1.79oz KTR-209: 2.70oz	Main Unit: P.T.S-II: 75g P.T.S-IIA: 100g P.T.S-IIB: 100g 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	SE Note 1
Dimensions of main unit (mm)	Model KTR-2401: Φ46.3x12.07; Model KTR-2402: Φ46.28x11.69 Model KTR-2411: 46.29x46.29x12.08; Model KTR-2412: 46.29x46.29x11.59; Model KTR-2301: Φ49.8x12.44; Model KTR-2302: Φ49.8x12.48 Model KTR-2341: 48.8x48.8x12.42; Model KTR-2342: 48.8x48.8x12.45;	36 x 35 x 13.7 mm	KTR-206: 112.5x59x33.3mm KTR-208: 112.5x59x29.5mm	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	SE Note 1

Elements of Comparison	Subject Device	Predicate Device 1 (primary)	Predicate Device 2	Predicate Device 3	Remark
	Model KTR-2491: Φ49.8x12.44; Model KTR-2492: Φ49.8x12.48 Model KTR-2493: 48.8x48.8x12.42; Model KTR-2494: 48.8x48.8x12.45;		KTR-209: 129.7x60x17. 8mm	Electrode A (only for CP-I): 450 x 450 x 90 mm Sole Plant Electrode B: 450 x 450 x 90 mm	
Housing Materials and Construction	Main unit: ABS plastic	Retardant Polycarbonate	Main unit: ABS plastic	Main unit: ABS plastic	SE
Waveform	Pulsed, symmetric, biphasic	Monophasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	SE
Shape	Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval	Rectangular	SE
Maximum Output Voltage	43.6V±10% @ 500Ω	(±10%) @ 500Ω • Mode 1: 64V • Mode 2: 67V • Mode 3: 59V • Combination : This mode cycles the above modes	KTR-206: 49.6V@ 500Ω 68.5V @ 2kΩ 73V @ 10kΩ	40V±10% @ 500Ω	SE Note 2
	59V±10% @ 2KΩ	(±10%) @ 2KΩ • Mode 1: 113 V • Mode 2: 119 V • Mode 3: 108 V • Combination: This mode cycles the above modes.	KTR-208: 58.5V @ 500Ω 70V @ 2kΩ 70.5V @ 10kΩ	80V±10% @ 2KΩ	
	66.5V±10% @ 10KΩ	(±10%) @ 10KΩ <15	KTR-209: 62V @ 500Ω 80V @ 2KΩ 84V @ 10KΩ	95V±10% @ 10KΩ	
Maximum Output Current	87.2mA±10% @ 500Ω	(±10%) @ 500Ω • Mode 1 : 128 mA • Mode 2 : 134 mA • Mode 3 : 118 mA • Combination: This mode cycles the above modes.	KTR-206: 99.2mA @ 500Ω 34.25mA @ 2KΩ 7.3mA @ 10KΩ	80mA±10% @ 500Ω	SE Note 2
	29.5mA±10% @ 2KΩ	(±10%) @ 2KΩ • Mode 1: 57 mA	KTR-208: 117mA @ 500Ω	40mA±10% @ 2KΩ	

Elements of Comparison	Subject Device	Predicate Device 1 (primary)	Predicate Device 2	Predicate Device 3	Remark
		• Mode 2: 60 mA • Mode 3: 54 mA • Combination: This mode cycles the above modes.	35mA @ 2KΩ 7.05mA @ 10KΩ		
	6.65mA±10% @ 10KΩ	(±10%) @ 10KΩ <15	KTR-209: 124mA @ 500Ω 40mA @ 2KΩ 8.4mA @ 10KΩ	9.5mA±10% @10KΩ	
Pulse Duration	120μs	(±10%) • Mode 1: 115 μs • Mode 2: 75 μs • Mode 3: 65 μs • Combination: This mode cycles the above modes.	KTR-206: 84μs-134μs KTR-208: 82μs-128μs KTR-209: 80μs-224μs	200μs	SE Note 2
Pulse frequency	20-100Hz	(±10%) • Mode 1: 2Hz • Mode 2: 16.7Hz • Mode 3: 33.3Hz • Combination: This mode cycles the above modes.	KTR-206: 1Hz-108Hz KTR-208: 1Hz-109Hz KTR-209: 1Hz-110Hz	13.7~48.5Hz	SE Note 2
Net Charge (per pulse)	0μC @ 500Ω, Method: Balanced waveform	Unknown	0μC @ 500Ω, Method: Balanced waveform	0μC @ 500Ω, Method: Balanced waveform	SE
Maximum Phase Charge	12.66μC @ 500Ω	(±10%) @ 500Ω • Mode 1: 14.72 μC • Mode 2: 10.05 μC • Mode 3: 7.67 μC • Combination: This mode cycles the above modes.	KTR-206: 12.32μC @ 500Ω KTR-208: 18.12μC @ 500Ω KTR-209: 33.07μC @ 500Ω KTR-208:6.89mA KTR-209: 12.39mA	19.3μC @ 500Ω	SE Note 2
Maximum Current Density(mA/cm2, r.m.s.) (@500Ω)	0.058 (mA/cm²)	(±10%) <Standard Electrode: 12.57cm²> • Mode 1: 0.154 • Mode 2: 0.377 • Mode 3: 0.437 • Combination: This mode cycles the	KTR-206: 0.26mA/cm² KTR-208: 0.22mA/cm² KTR-209: 0.4mA/cm²	0.073mA/cm²	SE Note 2

Elements of Comparison	Subject Device	Predicate Device 1 (primary)	Predicate Device 2	Predicate Device 3	Remark
		above modes. <Monarch Electrode: 38.09 cm^2> • Mode 1: 0.051 • Mode 2: 0.124 • Mode 3: 0.144 • Combination: This mode cycles the above modes.			
Maximum Average Power Density(@500Ω)	0.037 (mW/cm^2)	(±10%) <Standard Electrode: 12.57cm^2> • Mode 1: 0.15 • Mode 2: 0.893 • Mode 3:1.2 • Combination: This mode cycles the above modes. <Monarch Electrode: 38.09 cm^2> • Mode 1: 0.049 • Mode 2: 0.295 • Mode 3: 0.396 • Combination: This mode cycles the above	KTR-206: 0.001W/cm^2 KTR-208: 0.0008W/cm^2 KTR-209: 0.0025W/cm^2	0.056mW/cm^2	SE Note 2
Environment for operating	Environment temperature: +5°C-+40°C; Environment humidity: 0%-80%RH; Atmospheric environment conditions: 860hPa-1060hPa.	Unknown	Environment temperature: +5°C-+40°C; Environment humidity: 0%-80%RH; Atmospheric environment conditions: 860hPa-1060hPa.	Temperature: 5~40°C, Humidity: ≤80%RH, Atmospheric Pressure: 86~106kPa	SE
Environment for storage	Environment temperature: 0°C-+55°C; Environment humidity: 0-93%RH; Atmospheric environment conditions: 500hPa-1060hPa.	Unknown	Environment temperature: 0°C-+55°C; Environment humidity: 0-93%RH; Atmospheric environment conditions: 500hPa-1060hPa.	Temperature: Main Unit: -20~55°C, Electrode Pad: 10~20°C Humidity: 10~95% RH, Atmospheric Pressure: 50~106 kPa	SE
Biocompa	All user directly	-ISO 10993-5:	All user directly	All user directly	SE

Elements of Comparison	Subject Device	Predicate Device 1 (primary)	Predicate Device 2	Predicate Device 3	Remark
tibility	contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Cytotoxicity Test (Aggar Diffusion Assay) - ISO 10993-10: Primary skin irritation study in rabbits (4 hour semi-occlusive application) - ISO 10993-10: Contact Hypersensitivity in Albino Guiana Pigs Maximization Test	contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	
Electrical Safety	Comply with IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10	Comply with IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10	Comply with IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
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

Comparison in Detail(s):

Note 1:
Although the “Power source”, “Weight” , “Dimensions of main unit (mm)” are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

Note 2:
Although the “Number of Output Modes”, “Maximum Output Voltage”, “Maximum Output Current”, “Pulse Duration”, “Pulse frequency”, “Maximum Phase Charge” “Maximum Average Current", “Maximum Current Density(r.m.s)” and “Maximum Average Power Density” of subject device are little different from the predicate device, their maximum peak voltage are very similar, and are all comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Final Conclusion:
Based on the above analysis and tests performed, it can be concluded that the performance and function of the Transcutaneous Electronic Nerve Stimulator is Substantially Equivalent (SE) to the primary predicate device.

9. Date of the summary prepared: October 14, 2020