September 25, 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: K191982
Trade/Device Name: 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)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: March 20, 2020
Received: June 29, 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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191982

Device Name
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)

Indications for Use *(Describe)*
KTR-2210, KTR-2220, KTR-2230:（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 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.

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
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- Contact Person: Zewu Zhang (General Manger)
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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

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3. Subject Device Information

- Trade Name: 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)
- 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, NGX**
- Regulation Class: II
- Regulation Number: 882.5890, 890.5850

4. Predicate Device Information

	Primary Predicate Device	Reference Device 1	Reference Device 2
Sponsor	Shenzhen OSTO Technology Company Limited	Guangzhou Xinbo Electronic Co., Ltd.	Shenzhen OSTO Technology Co., Ltd.
Device	Health Expert Electronic	Pain Therapy Device	Intelligent Wireless Fitness Apparatus

Name and Model	Stimulator, Model: AST-300C and AST-300D	Models:P.T.S-11, P.T.S-IIA, P.T.S-118 , CP-I	Models: AST-301, AST-302, AST-303
510(k) Number	K133929	K163611	K182136
Product Code	NUH, NGX	**NUH, NGX**	NGX
Regulation Number	882.5890, 890.5850	882.5890, 890.5850	890.5850
Regulation Class	II	II	II

5. Device Description

Low-frequency Multi-function physiotherapy instrument (Models: KTR-2210) is a portable and battery powered multifunctional device, offering Transcutaneous Electronic Nerve Stimulator (TENS), Electronic Muscle Stimulator (EMS) and FITNESS qualities.

Low-frequency Multi-function physiotherapy instrument (Models: KTR-2210) has 50 operation modes, which can give certain electrical pulse through 4 pcs of electrode pads placed on the skin to help users to enjoy body massage.

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. All the accessories, including electrode pads, electrode wire, and batteries can only be changed by special person.

The electrode pads are complying with the biocompatibiilty standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization), are interchangeable.

6. Intended Use / Indications for Use

KTR-2210, KTR-2220, KTR-2230: CTENS, 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 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.

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
- 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 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**	**Primary Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
Device Name and Model	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	Low-frequency Multi-function physiotherapy instrument Model: AST-300C and AST-300D	Pain Therapy Device, Models: P.T.S-11, P.T.S-IIA, P.T.S-11B, CP-I	Intelligent Wireless Fitness Apparatus Models: AST-301, AST-302, AST-303	
510(k) Number	Applying	K133929	K163611	K182136	
Intended Use	**KTR-2210 , KTR-2220 , KTR-2230 : (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	**PMS (Mode** 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist,	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	Intelligent Wireless Fitness Apparatus is indicated to be used for: Improvement of abdominal tone, strengthening of the abdominal	SE Note 1

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
	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 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.	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.	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 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	muscles development of firmer abdomen. Strengthening, toning and firming of buttocks and thighs.	
Power Source(s)	**DC 4.5V (3*AAA LR03** battery), 180mA	Adaptor Input 100-240Vac, 50-60Hz, 0.1A Output 5Vdc, 1A Unit Input 5Vdc, 1A	DC 3.0V, 2 x AAA	Adapter (Model HDMU05E-050100, HDMU05B-050100, HDMU05U-050100) Input 100-240 Vac; 50/60 Hz; **0,3A;**	SE Note 2

Elements of Comparison		Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
					Output: 5 V; 1A 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	AC: 54.5µA, DC: 0.5µA	DC: 0.5µA	< 0 .01µA	SE
	SFC	DC: 0.6µA	AC:120.0 µ A , DC: 0.6µA	DC: 0.6µA	0.1mA	
Average DC current through electrodes when device is on but no pulses are being applied		< 0 .01 µA	< 0 .01µA	< 0 .01	Not publicly available	SE
Number of Output Ch annel s:		2 h c anne1s	2 channels	2	2	SE
Number of Output Modes		50	25	3	8	SE Note 3
Output Intensity Level		16 steps	99 steps	5 steps	Not publicly available	SE Note 3
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 **" BodyT"** and **" Body T"** buttons for body channel, "Sole .& " and **"SoleT"** buttons for feet channel	Parallel connection	Voltage Transform Isolation	SE Note 3
Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Parallel connection	Voltage Control	SE

Elements of Comparison		Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
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	No	No	No	Yes	SE
	Voltage/ Current Level	Yes	Yes	Yes	Yes	SE
Timer Range		15, 30, 45min	25min	10, 20, 40 min	15 min	SE Note 3
Weight		KTR-2210, KTR-2211, KTR-2212: 76g KTR-2220, KTR-2221, KTR-2222: 82g KTR-2230, KTR-2231, KTR-2232: 75g Electrode :12g Electrode wire: 12g	2Kg (Without accessories)	Main Unit: P.T.S-I: 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	80g (Without accessories)	SE Note 4

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
			Electrode B: 920g		
Dimensions	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)	428mm x 428.8mm x 185mm	Main Unit: P.T.S-11: 110 x 78 x 20mm P.T.S-IIA: 135 x 82 x20 mm P.T.S-IIB: 135 x 82 x20 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 x2mm Each gel sheet 90mm x60mm x2mm	SE Note 4
Housing Materials and Construction	. . . Mam urnt: 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	Rectangular , with interphase interval	SE
Maximum Output Voltage	55V±10%@ 500 Ω	44V±10% @ 500 Ω	40V±10% @ 500 Ω	44V±10%@ 500 Ω	SE Note 3
	75V±10% @ 2K Ω	80V±10% @ 2K Ω	80V±10% @ 2K Ω	80V±10%@ 2K Ω	

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
	85V±10% @ 10K Ω	112V±20% @ 10K Ω	95V±10%@ 10K Ω	112V± 20 % @ 10K Ω	
Maximum Output Current	110mA±10%@ 500 Ω	88mA±10% @ 500 Ω	80mA±10% @ 500 Ω	88mA±10% @ 500 Ω	SE Note 3
	37.5mA±10% @ 2K Ω	40mA±10% @ 2K Ω	40mA±10%@ 2K Ω	40mA±10%@2K Ω	
	8.5mA±10%@ 10K Ω	11.2mA±10% @ 10K Ω	9.5mA±10% @10K Ω	11.2mA±10% @10K Ω	
Pulse Duration	TENS: 120μs, EMS: 200μs, FITNESS: 200μs	120μs	200μs	120μs	SE Note 3
Pulse frequency	TENS:(20-100)Hz, EMS:(1-15)Hz, FITNESS:(2-16)Hz	77.3Hz	13.7~48.5Hz	8.33Hz	SE Note 3
Net Charge (per pulse)	0μC@500 Ω Method: Balanced waveform	0μC @500 Ω Method: Balanced waveform	0μC @ 500O, Method: Balanced waveform	10.56μC @ 500Ω	SE
Maximum Phase Charge	15.97 μC@ 500 Ω	12.78μC @ 500 Ω	19.2μC @ 500 Ω	12.78μC @ 500Ω	SE Note 3
Maximum Average Current	1.60mA	0.968mA @ 500 Ω	1.53mA @ 500 Ω	1.69mA @ 500 Ω	SE Note 3
Maximum Current Density (r.m.s)	0.064mA/cm^2 @ 500 Ω	0.235mA/cm^2 @500 Ω	0.073mA/cm^2 @500 Ω	0.26 mA/cm^2 @500 Ω	SE Note 3
Maximum Average Power Density	0.08mW/cm^2	1.38mW/cm^2 @ 500 Ω	0.056m W/cm^2 @500 Ω	15.37μW/cm^2 @500 Ω	SE Note 3
ON Time	0.6s	0.6s	2s	3s	SE
OFF Time	0.6s	0.6s	23s	3s	SE
Environment for operating	Environment temperature : +5°C-+40 C; Environment humidity: 15%-93%RH	**Temperature: 5 ~ 45°C Hu midity: 20 ~ 65% RH**	Temperature **5~40°C, Humidity: ::;a0 %RH,** Atmospheric Pressure:	**0°C to +40°C**	SE Note 5

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device 1	Reference Device 2	Remark
	Atmospheric environment conditions: 700hPa-1060hPa		86~106kPa		
Environment for storage	Environment temperature: -25°C-+70°C; Environment humidity: 0-93%RH; Atmospheric environment conditions: 700hPa-1060hPa.	Temperature: 0 ~ 45°c , Humidity : 10 ~ 90% RH Electrode Pad: 10~20°C	Temperature: Main Unit: -20~55°C, Electrode Pad: 10~20°C Humidity: 10~95% RH, Atmospheric Pressure: 50~106 kPa	Not publicly available	SE Note 5
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Allus e_ r directly. contacting materials are compliance with ISO10993-5 and ISO10993-10 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
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 "intended use" are a little different from the predicate device, but the Indications and applicable parts are same, and the differences will not raise any safety or effectiveness issue.

Note 2:

Although the "power source" is a little different from the predicate device, they are all comply with IEC 60601-1 and IEC 60601-2-10 requirements, and the differences will not raise any safety or effectiveness issue.

Note 3:

Although the "Number of Output Modes", "Output Intensity Level "," Method of Channel Isolation", "Timer Range", "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.

Note 4:

Although the "Weight" and "Dimensions" are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

Note 5: Although the "Environment for operating" and "Environment for storage s" are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject devices "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" are Substantial Equivalent to the predicate device K133929. For the differ pulse duration of 200μs, the subject device are compared with the reference device K163611, and there is no any safety or effectiveness issue.