January 26, 2018

Shenzhen Conree Technology Co.,Ltd
% Jet Li
Regulation manager
Guangzhou LETA Testing Technology Co., Ltd
6F, No.1 TianTai road, Science City
LuoGang District
Guangzhou, Guangdong, China

Re: K172933
Trade/Device Name: Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE (Model KRES100B)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, NUH
Dated: January 14, 2018
Received: January 19, 2018

Dear Jet Li:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172933

Device Name
Mini TENS DEVICE (Model: KRES102), TENS &EMS DEVICE (Model: KRES100B)

Indications for Use *(Describe)*
Mini TENS Device (Model KRES102) is to be used for the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities.
TENS & EMS Device (Model KRES100B) has two functions and can be used for arm, shoulder, neck, back, waist, abdomen, and leg.
TENS: It is used for the symptomatic relief of chronic intractable pain and the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities.
EMS: It is used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

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. Date of the summary prepared: 2017-08-15

There is no prior submission for this device.

2. Submitter's Information

Company Name: Shenzhen Conree Technology Co.,Ltd
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Application Correspondent:

Company: Guangzhou Keyda Testing Technology Co., Ltd.
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Contact Person: Mr. Jet Li
Tile: Regulation Manager
Tel: +86-20-22325619
Email: med-jl@foxmail.com

3. Subject Device Information

a)Type of 510(k) submission: Traditional

Common Name: Stimulator, muscle, powered; stimulator, nerve, transcutaneous, for pain relief ; Stimulator, nerve, transcutaneous, over-the-counter

Trade Name: TENS &EMS DEVICE (Model: KRES100B)

Classification Name: Powered muscle stimulator; Transcutaneous electrical nerve stimulator for pain relief

Review Panel: Physical Medicine; Neurology

Product Code: IPF, GZJ, NUH

Regulation Number: 890.5850**,** 882.5890

Regulation Class: 2

b)Type of 510(k) submission: Traditional

Common Name: Stimulator, nerve, transcutaneous, over-the-counter

Trade Name: Mini TENS DEVICE (Model: KRES102)

Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Review Panel: Physical Medicine; Neurology

Product Code: NUH

Regulation Number: 882.5890

Regulation Class: 2

4. Predicate Device Information

Sponsor	Famidoc Technology Co., Ltd	Famidoc Technology Co., Ltd	SHENZHEN KENTRO MEDICAL ELECTRONICS CO., LTD	Shenzhen OSTO Technology Company Limited
Device Name	FDES101 (ED4O1) TENS and EMS Stimulator	FDES1O5(ED405) Pain Relief Plaster	KTR-203	Electronic Stimulator, Model: AST-300C and AST-300D
510(k) Number	K113010	K130723	K170205	K133929
Product Code	IPF,GZJ,	NUH	NUH	NUH
Regulation Number	890.5850; 882.5890	882.5890	21 CFR 882.5890	882.5890, 890.5850
Regulation Class	2	2	2	2

5. Device Description

Mini TENS DEVICE (Model: KRES102) is to be used for the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities. It is a transcutaneous electrical nerve stimulator. The output waveform is provided 5 programs and 10 adjustable intensity levels. The color of LED lamp is used to indicate the program which patients choose. The program (P1-P5) in KRES102 is identical to the program P1, P2, P3, P4 and P5 individually.

TENS&EMS DEVICE (Model: KRES100B) consists of three parts: Main unit, 4 electrode pieces, Electrode line. The device is a micro current stimulator, has 2 functions: TENS and EMS. It can be used for arm, shoulder, neck, back, waist, abdomen, and leg.

TENS: It is used for the symptomatic relief of chronic intractable pain and the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities. The output waveform is provided 12 programs and 40 adjustable intensity levels. The LCD screen shows the information of program, level, operating time and channel.

EMS: It is used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and has 10 programs. The output waveform is provided 10 programs and 40 adjustable intensity levels. The LCD screen shows the information of program, level, operating time and channel.

The electrode pads (KRES102: Model: 50x50mm^2, KRES100B: Model: 73x53mm^2) are cleared by FDA. The number is K152648 for the electrode pads. They are used as an accessory to the TENS or EMS device unit, which transmits electrical current to patient skin. The electrical current is first transmitted via the lead wire or snap button then transmitted to the conductive gel which is adhered to patient skin. The electrode pads are composed of a cover, connector lead wire or snap button, conductive carbon film, conductive hydrogel, and an electrode carrier liner. It is non-sterile and intended for single adult patient (age≧18) multiple application use.

6. Intended Use / Indications for Use

Mini TENS Device Model KRES102 is to be used for the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities.

TENS & EMS Device Model KRES100B has two functions and can be used for arm, shoulder, neck, back, waist, abdomen, and leg.

TENS: It is used for the symptomatic relief of chronic intractable pain and the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities.

EMS: It is used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

7. Test Summary

For Mini TENS DEVICE (Model: KRES102):

The device has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 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"
- Waveform test report to verify the output specifications of the device according to IEC 60601-2-10 and Guidance for Powered Muscle Stimulator.

For TENS&EMS DEVICE (Model: KRES100B) :

The device has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 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"
- Waveform test report to verify the output specifications of the device according to IEC 60601-2-10 and Guidance for Powered Muscle Stimulator.

8. Non-clinical studies and tests performed:

Non-clinical tests have been conducted to verify that the device 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 K152648 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, 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. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the Mini TENS DEVICE (Model: KRES102), TENS & EMS DEVICE Model: KRES100B is substantially equivalent to the predicate devices quoted above.

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

For Mini TENS DEVICE (Model: KRES102):

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Device Name and Model	Mini TENS DEVICE Model: KRES102	FDES105(ED405) Pain Relief Plaster	KTR-203	Health Expert Electronic Stimulator Model: AST-300C and AST-300D	--
510 (K) Number	Applying	K130723	K170205	K133929	--
Product Code	NUH	NUH	NUH	NUH	--
Regulation Number	882.5890	882.5890	882.5890	882.5890(for TENS)	--
Intended Use	Mini TENS DEVICE (Model: KRES102) is to be used for the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities	FDES105(ED405) Pain Relief Plaster To be used for temporary relief of pain associated with sore and aching muscles 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, waist, back, arm, leg and foot, due to strain from exercise or normal household and work activities.	TENS (Mode 9~25) 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	SE

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
				applying current to stimulate nerve.	
Apply parts	Arm, shoulder, neck, back, neck, waist, abdomen, and leg	Low back, upper extremities (arm), and lower extremities (leg)	shoulder, waist, back, arm, leg and foot	shoulder, waist, back, back of the neck, arm, leg, and foot	SE
Power Sources	3.0V\210mAh Button lithium manganese battery	DC 3V, 2 X AAA Batteries	AAA batteries	External adapter	SE Note 1
Method of Line Current Isolation	Battery Supply	Battery Supply	Battery Supply	Insulation in the external adapter	SE Note 1

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Number of Modes for Micro current stimulation	5	5	5	25	SE
Number of Channels for Micro current stimulation	1	1	--	2	SE
Synchronous or Alternating	N/A	N/A	--	Synchronous	SE
Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	SE
Software/Firmware/ Microprocessor control	Yes	Yes	Yes	Yes	SE
Automatic Overload Trip	Yes	Yes	Yes	No	SE

Elements of Comparison		Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Automatic No-load Trip		Yes.	Yes	Yes	No	SE
Automatic Shut Off		Yes.	Yes	Yes	Yes	SE
Patient Override Control		Yes	Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	Yes	
	Low Battery	No	No	--	No	

Elements of Comparison		Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
	Voltage/ Current Level	NO	NO	--	Yes	
Timer Range		30 minutes	Nonadjustable 30 minutes	--	25 minutes	SE Note 2
Console weight		20 g	0.093lbs.oz	1.7oz	2Kg (Without accessories)	SE Note 3
Housing Materials and Construction		Console: ABS plastic	Plastic (ABS) enclosure	Plastic (ABS) enclosure	Main unit: ABS plastic	SE
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	SE

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Shape	Rectangular	Rectangular	Rectangular	Rectangular	SE
Maximum Output Voltage (+/- 10%)	28.2V @500Ω 48.4V @ 2kΩ 82V @ 10kΩ	28V@500Ω 36.8V@2KΩ 41.6V@10KΩ	44V@500ohm 58V@2kohm 63.5V@10kohm	44V±10% @ 500Ω; 80V±10% @ 2KΩ; 112V±10% @ 10KΩ	SE Note 4
Maximum output Current	56.4mA@500Ω 24.2mA @ 2kΩ 8.2mA@10kΩ	56mA @ 500Ω 18.4mA @ 2kΩ 4.2mA @ 10kΩ	88mA@500ohm 29mA@2kohm 6.35mA@10kohm	88mA±10% @ 500Ω; 40mA±10% @ 2KΩ; 11.2mA±10% @ 10KΩ	SE Note 4
Frequency range	1~117.3Hz	2~80HZ	1-200Hz	77.3Hz	SE Note 5
Pulse width range	90~260μs	200~250μs	50-220us	120μs	SE Note 5
Net Charge	0uC @ 500Ω	15.2μC @ 500Ω	0μC @500ohm	0μC @ 500Ω Method: Balanced waveform	SE

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Maximum Current Density	0.025 mA/cm² @500Ω	4.1 mA/cm²	0.15mA/cm2@500ohm	0.235mA/cm² @ 500 Ω	SE Note 6
Maximum Power Density	12.21μW/cm² @500Ω	0.105W/cm2	0.56mW/cm2@500ohm	1.38mW/cm² @ 500 Ω	SE Note 6
ON time	N/A	N/A	No	0.6s	SE
OFF time	N/A	N/A	No	0.6s	SE
Contraction and Relaxation time	Adjustable, due to different modes.	Adjustable, due to different modes.	Adjustable, due to different modes.	Adjustable, due to different modes.	SE

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Environment for operating	Temperature: 5 ~ 40° C Relative humidity: 15%RH to 93% RH	Temperature: 5 ~ 40° C Relative humidity: 30%RH to 85% RH	--	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% RH	SE
Environment for storage	Temperature: -25° C ~ 70° C Relative humidity: 15%RH to 93% RH	Temperature: -10℃~50℃ Relative humidity: 10%RH to 90% RH	--	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20°C	SE
Biocompatibility	Compliant with requirements of ISO10993-5 and ISO10993-10 standards since the electrode pad had been FDA510K cleareance	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	SE

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device II	Predicate Device III	Remark
Electrical Safety	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	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 (Power Source(s) and Method of Line Current Isolation):

The design of the power source is according to the circuit design of the device, which should ensure the safety and effectiveness. Our product complies with IEC 60601-1 requirements which means it's safe, also, the performance of our devices is substantially equivalent with the predicated devices under this power supply condition, which would be discussed in the follow description. Therefore, the subject devices are actually the same as predicated ones.

Note 2 (Timer Range):

The design of the timer range is based on the intended use. For Mini TENS DEVICE, the different mode means different operating time.

Note 3 (Weight):

These data would be different for different devices because the internal circuit design and components choosing are different, which make them have similar difference on weight, dimensions. But weight and dimensions won't affect the safety and effectiveness of the device so it can deemed as the substantially equivalence.

Note 4 (Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation are determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject device from the predicated devices, it can still obtain the same effect because our output voltage and output current is in the range which is similar to the value of K130723. Also, the subject device comply with IEC 60601-1, and IEC60601-2-10 which means we have proved its safety as well as the effectiveness comparing with the predicate devices. Therefore, the subject device and predicate devices are substantially equivalence on output voltage and current.

Note 5 (Frequency and Pulse width):

The effect of micro current stimulation are determined by micro-current output waveform and output current. Frequency and pulse is the time parameter of the waveform. There is only little difference between the Frequency and pulse width of the subject device from the predicated device, it can still obtain the same effect because our output voltage and output current is in the range which is similar to the value of K130723. Also, the subject device complies with IEC 60601-1, and IEC60601-2-10 which means we have proved its safety as well as the effectiveness

comparing with the predicate devices. Therefore, the subject devices and predicate devices are substantially equivalence on these parameters.

Note 6 (Maximum current density and Maximum power density):

The effect of micro current stimulation are determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject device from the predicated devices, but the value of current density and maximum power density of subject device are in the range which is similar to the value K130723. And the maximum power density meet with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Finial Conclusion:

The subject device Mini TENS DEVICE (Model: KRES102) is Substantial Equivalence to the predicate devices.

For TENS&EMS DEVICE (Model: KRES100B) :

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
Device Name and Model	TENS & EMS DEVICE Model: KRES100B	FDES1O1(ED4O1) TENS and EMS Stimulator	KTR-203	Health Expert Electronic Stimulator Model: AST-300C and AST-300D	--
510 (K) Number	Applying	K113010	K170205	K133929	--

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
Product Code	IPF, GZJ, NUH	IPF, GZJ	NUH	NUH	Even some product code is not identical, but the regulation number is the same and its intended use is same.
Regulation Number	890.5850, 882.5890	890.5850, 882.5890	882.5890	882.5890	--
Intended Use	TENS & EMS Device Model KRES100B has two functions and can be used for arm, shoulder, neck, back, waist, abdomen, and leg. TENS: It is used for the symptomatic relief of chronic intractable pain and the temporary relief of pain associated with sore and aching	For TENS mode: 1. Symptomatic relief of chronic intractable pain 2. Post traumatic pain 3. post surgical pain For EMS mode 1 . Relaxation of muscle spasm. 2. Increase of local blood flow circulation 3. Prevention or retardation of disuse	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.	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, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
	muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities. EMS: It is used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.	atrophy 4. Muscle re-education. 5. Maintaining or increasing range of motion 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis		activities by applying current to stimulate nerve.	
Apply parts	Arm, neck, shoulder, back, waist, abdomen, leg.	Any area (Except those treatment area which been described in the user manual can not use), such as Hand., Arm. Chest. Waist. Buttock, Thigh, Calf.	shoulder, waist, back, arm, leg and foot	shoulder, waist, back, back of the neck, arm, leg, and foot	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
		back and low back etc.			
Power Sources	1.5Vx3, Model: AAA	DC 6V, 4 X 1. 5V AAA battery	AAA batteries	External adapter	SE Note 1
Method of Line Current Isolation	Battery Supply	Battery Supply	Battery Supply	Insulation in the external adapter	SE Note 1
Number of Modes for Micro current stimulation	TENS: 12 EMS: 10	30	5	25	SE
Number of Channels for Micro current stimulation	2	2	--	2	SE
Synchronous or Alternating	Synchronous	Synchronous	--	Synchronous	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
Regulated Current or Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	Regulated Voltage	SE
Software/Firmware/Microprocessor control	Yes	Yes	Yes	Yes	SE
Automatic Overload Trip	Yes	Yes	Yes	No	SE
Automatic No-load Trip	Yes.	Yes	Yes	No	SE
Automatic Shut Off	Yes.	Yes	Yes	Yes	SE
Patient Override Control	No	No	Yes	Yes	SE

Elements of Comparison		Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
Indicator Display	On/Off Status	Yes	Yes	Yes	Yes	SE
	Low Battery	Yes	--	No	Yes	SE
	Voltage/ Current Level	NO	--	Yes	NO	SE
Timer Range		5~30 minutes	0-60 minutes	--	25 minutes	SE Note 2
Console weight		120g	0.36 lbs	1.7oz	2Kg (Without accessories)	SE Note 3

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
Housing Materials and Construction	Console: ABS plastic	ABS	Plastic (ABS) enclosure	Main unit: ABS plastic	SE
Waveform	Biphasic	Biphasic	Biphasic	Biphasic	SE
Shape	Rectangular	Rectangular	Rectangular	Rectangular	SE
Maximum Output Voltage (+/- 10%)	43.2V @ 500Ω 64V @ 2kΩ 106V @ 10kΩ	60V@1000Ω	44V@500ohm 58V@2kohm 63.5V@10kohm	44V±10% @ 500Ω; 80V±10% @ 2KΩ; 112V±10% @ 10KΩ	SE Note 4

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
Maximum output Current	86.4mA @ 500Ω 32mA @ 2kΩ 10.6mA @ 10kΩ	0-60mA adjustable (at 1000 ohm load).	88mA@500ohm 29mA@2kohm 6.35mA@10kohm	88mA±10% @ 500Ω; 40mA±10% @ 2KΩ; 11.2mA±10% @ 10KΩ	SE Note 4
Frequency range	For TENS: 2~119.17HZ For EMS: 20.01~99.72HZ	0.5-150H-z	1-200Hz	77.3Hz	SE Note 5
Pulse width range	TENS: 96~260μs; EMS: 150~260μs	50-300uS	50-220us	120μs	SE Note 5
Pulse duration	TENS: 8.4~2080ms EMS:	--	0μC @500ohm	0μC @ 500Ω Method: Balanced waveform	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
	10~52ms				
Net Charge	0uC @ 500Ω	--	0.15mA/cm2@500ohm	0.235mA/cm² @ 500 Ω	SE
Maximum Current Density	TENS: 0.065mA/cm²@ 500Ω EMS: 0.063mA/cm²@ 500Ω	--	0.56mW/cm²@500ohm	1.38mW/cm² @ 500 Ω	SE Note 6
Maximum Power Density	TENS: 52.94μW/cm²@ 500Ω EMS: 48.92μW/cm²@ 500Ω	N/A	No	1.38mW/cm² @ 500 Ω	SE Note 6
ON time	TENS: N/A EMS: 5~20.1 seconds	N/A	No	0.6s	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
OFF time	TENS: N/A EMS: 0~15.2seconds	N/A	Adjustable, due to different modes.	0.6s	SE
Contraction and Relaxation time	Adjustable, due to different modes.	Adjustable, due to different modes.	--	Adjustable, due to different modes.	SE
Environment for operating	Temperature: 5 ~ 40° C Relative humidity: 30%RH to 85% RH	Temperature: 5 ~ 40° C Humidity: 30-75% RH Atmosphere Pressure: 700 ~1060hPa	--	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% RH	SE
Environment for storage	Temperature: -10 ℃ ~55℃ Relative humidity: 20%RH to 93%RH	Temperature: -10 ~ 50° C Humidity: 10- 90% RH Atmosphere Pressure:	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20°C	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	Remark
		700 ~ 1060hPa			
Biocompatibility	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	SE
Electrical Safety	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	Comply with IEC 60601-1-2: 2007 and IEC 60601-2-10: 2012 and IEC 62133	Comply with IEC 60601-1-2	Compliant with requirements of IEC 60601-1, IEC60601-2-10, IEC60601-1-2 safety standards	SE

Elements of Comparison	Subject Device	Predicate Device (Primary)	Predicate Device II	Predicate Device III	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

Note 1 (Power Source(s) and Method of Line Current Isolation):

The design of the power source is according to the circuit design of the device, which should ensure the safety and effectiveness. Our products comply with IEC 60601-1 requirements which means it's safe, also, the performance of our devices is substantially equivalent with the predicated devices under this power supply condition, which would be discussed in the follow description. Therefore, the subject devices are actually the same as predicated ones.

Note 2 (Timer Range):

The design of the timer range is based on the intended use. For TENS&EMS DEVICE, the user could adjust the time by the modes based on user instruction.

Note 3 (Weight):

These data would be different for different devices because the internal circuit design and components choosing are different, which make them have similar difference on weight, dimensions. But weight and dimensions won't affect the safety and effectiveness of the device so it can deemed as the substantially equivalence.

Note 4 (Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation are determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject devices from the predicated devices, it can still obtain the same effect because our output voltage and output current is in the range which is similar to the value of K143268, K130723 and K162479. Also, the subject devices complies with IEC 60601-1, and IEC60601-2-10 which means we have proved its safety as well as the effectiveness comparing with the predicate devices. Therefore, the subject device and predicate devices are substantially equivalence on output voltage and current.

Note 5 (Frequency and Pulse width):

The effect of micro current stimulation are determined by micro-current output waveform and output current. Frequency and pulse is the time parameter of the waveform. There is only little difference between the Frequency and pulse width of the subject devices from the predicated devices, it can still obtain the same effect because our output voltage and output current is in the range which is similar to the value of K143268, K130723 and K162479. Also, the subject devices comply with IEC 60601-1, and IEC60601-2-10 which means we have proved its safety as well as the effectiveness comparing with the predicate devices. Therefore, the subject devices and predicate devices are substantially equivalence on these parameters.

Note 6 (Maximum current density and Maximum power density):

The effect of micro current stimulation are determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject device from the predicated devices, but the value of current density and maximum power density of subject device are in the range which is similar to the value of K143268, K130723 and K162479. And the maximum power density meet with the

maximum allowed value 0.25 (W/cm²) required in FDA guidance. Therefore, the subject devices and predicate devices are substantially equivalence on these parameters.

Finial Conclusion:

The subject device TENS&EMS DEVICE (Model: KRES100B) are Substantial Equivalence to the predicate devices.