September 13, 2022

Shenzhen Future Electronic Co., Ltd
℅ You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd
RM. 1711, Building K, No. 101 Science Ave International
Creative Valley
Guangzhou, Guangdong 510663
China

Re: K221092
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator Model: ST-304
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 12, 2022
Received: August 12, 2022

Dear You Yijie:

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,

Pamela D. 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)*

K221092

Device Name
Transcutaneous Electrical Nerve Stimulator Model: ST-304

Indications for Use *(Describe)*
To be used for temporary relief of pain associated with sore and aching muscles in the back of neck, due to strain from exercise or normal household and work activities.
- Neck Pad is used in back of neck.

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

1. Submitter's Information

Establishment Registration Information

Name: SHENZHEN FUTURE ELECTRONIC CO.,LTD
Address: Bldg B. Qiangchengda Industrial Park, No. 30, Youtian Road, Longgang SHENZHEN Guangdong, CN 518116
Registration Number: 3014344342

Contact Person of applicant

Name: Zhao Qihong
Address: Bldg B. Qiangchengda Industrial Park, No. 30, Youtian Road, Longgang SHENZHEN Guangdong, CN 518116
TEL: +86-134 1094 7296
FAX: +86-134 1094 7296
Email: zhaoqihong@futuresz.com.cn

Contact Person of the Submission:

Name: Yijie You
Address: RM.1711, Building K, No.101 Science Ave International Creative Valley Development Zone, Guangzhou China
TEL: +86 020-8224 5821
FAX: +86 020-8224 5821
Email: Jet.you@qimmiq-med.com

Date prepared: Mar. 4, 2022

2. Device Information

Trade Name:	Transcutaneous electrical nerve stimulator
Model:	ST-304
Regulation name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Review Panel:	Neurology
Product Code:	NUH
Regulation Class:	II
Regulation Number:	21CFR 882.5890

3. Predicate Device Information

Primary Predicate Device

510(k) submitter/holder:	Shenzhen OSTO Technology Company Limited
510(K) Number:	K210756
Trade Name:	Neck Care Therapy
Model:	AST-905H
Classification name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Review panel:	Neurology
Product code:	NUH
Regulation Class:	II
Regulation Number:	21 CFR 882.5890

Secondary Predicate Device

510(k) submitter/holder:	Shenzhen OSTO Technology Company Limited
510(K) Number:	K172897
Trade Name:	Neck Care Therapy
Model:	905B
Classification name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Review panel:	Neurology
Product code:	NUH, NGX
Regulation Class:	II
Regulation Number:	21 CFR 882.5890, 890.5850

4. Device description

The subject device is intended to use on back of neck and it designed accord with human body cervical physiological curvature of streamlined ring design. It is a body-worn and home-use device. It uses low-frequency electronic therapy and designed to temporary relief of pain associated with sore and aching muscles in the back of neck. It only has one model: ST-304.

The trade name of the subject device is Transcutaneous electrical nerve stimulator.
The Transcutaneous electrical nerve stimulator (model: ST-304) consists of a main unit and Type C-USB charging cable. The main unit consists of shell, lithium battery (only 1pcs), neck electrodes pads (a pair of fixed neck electrodes pads), lower shell connector and control buttons and silicone pads. There are two fixed neck electrodes pads on the main unit. The material of neck electrodes pads is titanium material (Gr.2). There are only 1 pcs lithium battery in-build in main unit. The model of lithium battery is KRL 103040.
The neck electrodes pads (a pair of fixed neck electrodes pads) are a kind of Titanium material, and the detail content as following description and as the classify of ASTM F67 2017 it is under Gr2:

Titanium material (Gr.2)	Content		Value
	Main Components	Ti	Remainder

		Al	/			
		V	/			
	Impurity Elements	Fe	0.235			
		C	0.008			
		N	0.012			
		O	0.130			
		H	0.0043			
	Other Impurities		each	≤ 0.1	total	≤ 0.3

The Transcutaneous electrical nerve stimulator (model: ST-304) power supply is 3.7V DC using built-in lithium battery(1200mAh). The built-in lithium battery can be recharged. But the power adapter (Input: 100-240V~, 50/60Hz,0.7A, Output: 5V⎓1000mA) is not the parts of the subject device so it shall be supplied by the user. There are two fixed neck electrodes pads on the main unit. The material of neck electrodes pads is Titanium material (Gr.2).

The following power adapter is recommended:

Manufacturer: ShenZhen RiHuiDa Power Supply Co., Ltd

Model: RHD 10W050100U

UL certificate: E474213
Specification: Input: 100-240V~, 50/60Hz,0.7A
Output :5V⎓1000mA

The Transcutaneous electrical nerve stimulator (model: ST-304) totally has 3 modes. The stimulation has 2 modes for stimulating and 15 output Intensity Levels for each mode, so the device can give certain electrical pulse through the neck electrodes pads on the intact skin of back neck to help users to temporary relief of pain. The heating only has 1 mode for heating and it can also provide a constant temperature of 32℃ to 38℃ to provide a warming sensation. The stimulation function and heating function can be used separately or simultaneously. The neck electrodes pads provide users with back of neck stimulation and heat to warm and comfort the muscles of the back of neck.

The main unit provides access to adjust the intensity up or down and adjust stimulating mode, put ON/OFF the main unit and heating function.

The Intensity level of electrical stimulation and heating function are easily controlled by the end user using manual, push-button controls. The push-button controls are consisted of four button which are Switch on/off button/mode switch button, heating button, Intensity increase button and Intensity decrease button.

Button function description:

Switch on/off button/mode switch button( ):

1) Long press about (2 seconds) to turn on or turn off the Transcutaneous electrical nerve stimulator (model: ST-304) and sound “Di”. When turn on the device or in the working condition the button indicator light is blue and turn off the device button indicator will close.
2) When battery is low capacity(＜3.5V), the indicator of the button will be flashing in blue light 3 times for 5 seconds and with long “Di” sound every two minutes. At the same time when short press the button will sound “Di”. When the battery is charging the button will be flashing in green. When the battery is charged the button will be in green light always. The device can’t be used when it is charging.
3) When the capacity of battery＜3.1V, the device shown prompt sound, shut down.
4) Pulse mode adjusted:

Short press the button( ) to adjust pulse mode. When Mode 1 is chosen, the continuous "Di-Di-Di, Di-Di-Di, Di-Di-Di” sound about 3 second will be heard .When Mode 2 is chosen, intermittent " Di——,Di——， Di——" sound for 3 seconds will be heard.

Heating button ( )

1) Short press the button to start heating and button indication is green. If start heating successfully, the Transcutaneous Electrical Nerve Stimulator (ST-304) will sound “Di”. Short press to stop heating and button indication lights off, if stopping heating successfully, the Transcutaneous Electrical Nerve Stimulator (ST-304) will sound “Di Di”.

Intensity increase button ( ) and Intensity decrease button( )

1) Short press " ", " " button to add or subtract pulse intensity, 1-15 level adjustable. Level 1 is the lowest intensity and the Level 15 is the highest intensity.
2) After press " "or " " button, the sound “Di“ will be heard. When turn on the device, there is without any pulse output, after short press " " one time then enter into the working condition and will be output pulse in level 1 intensity. When the Intensity increase to 15 level, then short press the" " one more time will sound “Di Di”, it means the device is in the highest Intensity level (15 Intensity level).

The default stimulation time is 10 minutes, and the user cannot adjust but could turn off the device during working condition.
Transcutaneous electrical nerve stimulator (model: ST-304) has 2 types stimulation modes: Mode 1, Mode 2.

When turn on the device, the device turns into default setting, the stimulation mode is Mode 2 and there is without any pulse output, after short press " " one time then enter into the working condition and will be output pulse at level 1 intensity.

These stimulation modes can be selected by short pressing the Switch on/off button/mode switch button ( ). The two stimulation modes are the same in indication for use.

Before use the device to wipe the Electro Therapy Conductive Gel on the Neck Electrode Pads. But the Electro Therapy Conductive Gel is not the part of subject device so it shall be supplied by the user.

The following Electro Therapy Conductive Gel are recommended:

Manufacturer: Guangzhou Xinbo Electronic Co., Ltd.

Trade/Device Name: DR-HO'S Electro Therapy Conductive Gel

Model Name: DHGEL

FDA clearance with a 510(k) number: K200402

Accessory

Name	Specification/model	Quantity(pcs)
Type C -USB charging cable	length 1m, 24AWG(0.16*11)	1

Principle of operation:

The Transcutaneous electrical nerve stimulator (model: ST-304) sends low-voltage electrical pulses to specific nerves via two fixed neck electrodes pads applied on the intact skin of back of neck and powered by rechargeable lithium battery. The purpose is to temporarily relieve pain.

By adjusting the output voltage and frequency to produce the low-voltage electrical pulses and achieve the effect of electrotherapy. Voltage regulation is realized by the Boost Converter circuit, which controls the voltage amplitude by modifying the PWM control circuit. After that, the voltage is released to the electrode through the analog circuit, and the time change of the output voltage is controlled by modifying the PWM frequency to achieve the specific electrotherapy effect.

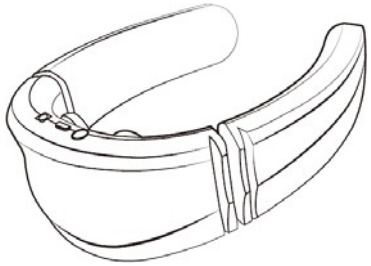
Note: PWM means Pulse Width Modulation

5. Indications for Use

To be used for temporary relief of pain associated with sore and aching muscles in the back of neck, due to strain from exercise or normal household and work activities.

- Neck electrodes Pads is used in back of neck.

6. Summary of technological characteristics of device compared to the predicate devices (K210756 and K172897)

Characteristic	**Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)**	**Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)**	**Predicate device 2 (K172897, Neck Care Therapy, 905B)**	**Discussion of difference**
Manufacturer	Shenzhen Future Electronic Co., Ltd	Shenzhen OSTO Technology Co., Ltd	Shenzhen OSTO Technology Co., Ltd	/
Picture				**/**
Classification	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890, 21 CFR 890.5850	**Same**
Prescription/OTC	OTC	OTC	OTC	**Same**
Product Code	NUH	NUH	NUH, NGX	**Same**
FDA Class	II	II	II	**Same**
Intended Use & Indications for Use	To be used for temporary relief of pain associated with sore and aching muscles in the back of neck, due to strain from exercise or normal	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back of neck, back, arm, and leg, due to strain	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back of neck, back,	**Same** Both of subject device and predicate devices can be used in back of neck.

Characteristic		Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)	Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)	Predicate device 2 (K172897, Neck Care Therapy, 905B)	Discussion of difference
		household and work activities. - Neck electrodes Pads is used in back of neck.	from exercise or normal household and work activities. - Neck Pad is used in back of neck. - Meridian Pad is used in shoulder, waist, back, arm and leg.	arm, and leg, due to strain from exercise or normal household and work activities. - Neck Pad is used in back of neck. - Meridian Pad is used in shoulder, waist, back, and arm.	
target population		adults	adults	adults	**Same**
Power Source		Main Unit: 3.7Vdc, 1200mAh Rechargeable lithium battery Power Adaptor: Input: 100-240V~, 50/60Hz,0.7A Output :5V⎓ 1000mA	Main Unit: 3.7Vdc, 2200mAh lithium battery Power Adaptor: Input: 100~240Vac, 50/60Hz, 0.2A; Output: 5Vdc, 1A Remote Control: Battery: 3Vdc, 1.5V, AAA x 2	Main Unit: Power Adaptor: Input:100~240Vac,50/60Hz, 0.2A; Output: 5Vdc, 1A Battery: 3.7Vdc, 500mAh Remote Control: Battery: 3Vdc, AAA x 2 Unit Input: 5Vdc,1A	**Different** See D1
Method of line current isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	**Same**
Patient Leakage Current	Normal condition	AC:23.3μA DC:≤1μA	AC:54.5μA DC:0.5μA	AC:54.5μA DC:0.5μA	**Different** See D2
	Single fault	AC: 6.7μA,	AC:120.0μA	AC:120.0μA	**Different**

Characteristic		**Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)**	**Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)**	**Predicate device 2 (K172897, Neck Care Therapy, 905B)**	**Discussion of difference**
	condition	DC: ≤1μA	DC:0.6μA	DC:0.6μA	See D2
Average current through electrodes when device is on but no pulses are being applied		< 0.01μA	< 0.01μA	< 0.01μA	**Same**
Number of Output Modes		3	3	2	**Same**
Output Intensity Level		For stimulating:15 For heating:1	For stimulating:50 For heating:3	50 steps	Different See D3
Heating temperature		32-38°C	30-40°C	NA	**Different** See D4
Number of Output Channels	Number	1	1	**1**	**Same**
	Synchronous or Alternating?	Synchronous	Synchronous	Synchronous	**Same**
	Method of Channel Isolation	Voltage Transform Isolation	Voltage Transform Isolation	Voltage Transform Isolation	**Same**
Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Voltage Control	**Same**
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	**Same**
Automatic Overload Trip?		No	No	No	**Same**
Automatic No-Load Trip?		No	No	**No**	**Same**

Characteristic		**Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)**	**Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)**	**Predicate device 2 (K172897, Neck Care Therapy, 905B)**	**Discussion of difference**
Automatic Shut Off?		Yes	Yes	Yes	**Same**
User Override Control?		Yes	Yes	Yes	**Same**
Indicator Display	On/Off Status?	Yes	Yes	Yes	**Same**
	Low Battery?	Yes	Yes	Yes	**Same**
	Voltage/ Current Level?	Yes	Yes	Yes	**Same**
Timer Range (minutes)		10min	5-30 min	5-30 min	**Different** See D5
ANSI AAMI ES60601-1 ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)		Yes	Yes	Yes	**Same**
ANSI AAMI ES60601-1-2 :2014		Yes	Yes	Yes	**Same**
IEC 60601-2-10 Edition 2.1 2016-04		Yes	Yes	Yes	**Same**
Weight		145g (only main unit)	For Main Unit: AST-905H: 178g For Electrode: Patch Electrode: 44g	**Main Unit:** **AST-905B: 222g** **Electrode:** **Patch Electrode: 44g**	**Different** See D6
Dimensions (mm) (W x H x D)		Main unit: 145 (W) × 140 (L) × 53 (H) (mm)	AST-905H: 173.4*156.3*43.4 mm For Electrode:	Main Unit: AST-905B: 187.2*169*67.3 mm Electrode: Patch Electrode: 8.9	**Different** See D7

Characteristic	**Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)**	**Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)**	**Predicate device 2 (K172897, Neck Care Therapy, 905B)**	**Discussion of difference**
	Neck electrode pad: 3,0cm×4,0cm Effective area for each Neck electrode pad:10cm^2	Meridian Pad: 8.9*5.8cm Effective area: 50.04cm^2 Neck Pad: 42.3 mm x29.5 mm	cm *5.8 cm	
Housing Materials and Construction	For Neck electrode pad: Titanium material (Gr2)	For Electrode Pads: White silica gel, Black conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone For Neck Pad: Stainless steel	Electrode Pads: White silica gel, Black conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone Sticky metal sheet: Stainless steel	**Different** See D8
	For Unit Housing: ABS Plastic and silica gel	For Unit Housing: ABS plastic	Housing unit: ABS plastic	

Output Specifications – Comparison with Predicate Devices

Characteristic	**Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)**	**Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)**	**Predicate device 2 (K172897, Neck Care Therapy, 905B)**	**Discussion of difference**
Waveform	**Mode 1:** Pulsed, symmetric, biphasic **Mode 2:** Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	**Same**
Shape (e.g., rectangular, spike, rectified sinusoidal)	**Mode 1:** Rectangular, with interphase interval **Mode 2:** Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular, with interphase interval	**Same**
Maximum Output Voltage (± 10%)	**Mode 1:** 44V @ 500 Ω 80V @ 2 kΩ 112V @ 10 kΩ **Mode 2:** 42V @ 500 Ω 78V @ 2 kΩ 105V @ 10 kΩ	44V±10% @ 500 Ω 80V±10% @ 2KΩ 112V±10% @ 10KΩ	44V±10% @ 500 Ω 80V±10% @ 2KΩ 112V±10% @ 10KΩ	**Different** **See D 9**
Maximum Output Current (± 10%)	**Mode 1:** 88mA @ 500 Ω 40mA @ 2 kΩ	88mA @ 500 Ω 40mA @ 2 kΩ 11.2mA @ 10 kΩ	88mA @ 500 Ω 40mA @ 2 kΩ 11.2mA @ 10 kΩ	**Different** **See D10**

Characteristic	Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)	Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)	Predicate device 2 (K172897, Neck Care Therapy, 905B)	Discussion of difference
	11.2mA @ 10 kΩ **Mode 2:** 84mA @ 500 Ω 39mA @ 2 kΩ 10.5mA @ 10 kΩ			
Pulse Width	**Mode 1:** 120 μs±10% **Mode 2:** 120 μs±10%	120 μs	120 μs	**Same**
Frequency	**Mode 1:** 77.3Hz ±10% **Mode 2:** 77.3Hz ±10%	77.3Hz	77.3Hz	**Same**
Net Charge (μC/pulse)	**Mode 1:** 0 μC @ 500Ω Method: balanced waveform **Mode 2:** 0 μC @ 500Ω Method: balanced waveform	0 μC @ 500Ω Method: balanced waveform	0 μC @ 500Ω Method: balanced waveform	**Same**
Maximum Phase Charge (μC)	**Mode 1:** 10.3μC@ 500Ω **Mode 2:**	10.56 (μC) @ 500Ω	12.78 (μC) @ 500Ω	**Different** **See D 11**

Characteristic		Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)	Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)	Predicate device 2 (K172897, Neck Care Therapy, 905B)	Discussion of difference
		9.6μC@ 500Ω			
Maximum Current Density, (mA / cm^2, r.m.s.) @ 500Ω		**Mode 1:** 2.2mA/cm^2 **Mode 2:** 2.2mA/cm^2	0.0326 mA/cm^2	0.235 mA/cm^2	**Different** **See D 12**
Maximum Average Power Density (mW/cm^2)		**Mode 1:** $0.36 mW/cm^2$@500Ω **Mode 2:** $0.32 mW/cm^2$@500Ω	0.0000266mW/cm^2 @500Ω	1.38 mW/cm^2	**Different** **See D 13**
Burst Mode (i.e., pulse trains)	Pulses per burst	N/A, no burst mode	Not public	Not public	**Different** **See D14**
	Bursts per second				
	Burst duration (seconds)				
	Duty Cycle [Line (b) x Line (c)				
ON Time (seconds)		240u s ± 10%	Not public	Not public	**Different** **See D 15**
OFF Time (seconds)		12.8ms ±10%	Not public	Not public	**Different** **See D 16**

Characteristic	**Subject device (Transcutaneous Electrical Nerve Stimulator, model ST-304)**	**Predicate device 1 (K210756, Neck Care Therapy, model: AST-905H)**	**Predicate device 2 (K172897, Neck Care Therapy, 905B)**	**Discussion of difference**
Operating Environment	Temperature: 10~38℃ Humidity: 30% -75%RH Atmospheric Pressure: 860 hPa -1060 hPa	Temperature: 10~40°C Humidity: 15% - 90%RH Atmospheric Pressure: 700 hPa to 1060 hPa	Temperature: 5~40°C Humidity: 15% - 90%RH Atmospheric Pressure: 700 hPa to 1060 hPa	**Different** **See D 17**
Storage Environment	Temperature: -25~70℃ Humidity: ≤90%RH Atmospheric Pressure: 860 hPa -1060 hPa	Temperature: -25~70℃ Humidity: ≤90%RH Atmospheric Pressure: 860 hPa -1060 hPa	Temperature: -25~70℃ Humidity: ≤90%RH Atmospheric Pressure: 860 hPa -1060 hPa	**Same**
Biocompatibility	Biocompatibility test according to ISO 10993-5 and ISO 10993-10	Biocompatibility test according to ISO 10993-5 and ISO 10993-10	Biocompatibility test according to ISO 10993-5 and ISO 10993-10	**Same**
Electrical Safety	Comply with ANSI AAMI ES60601-1: 2005/(R)2012 and A1: 2012 and IEC60601-2-10 Edition 2.1 2016-04	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	**Same**
EMC	Comply with ANSI AAMI IEC 60601-1-2:2014	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	**Same**

The discussion of differences exist between the subject and predicate device is listed in following:

D1: The subject device has demonstrated electromagnetic compatibility and electrical safety by ANSI AAMI ES60601-1 and ANSI AAMI IEC 60601-1-2 testing. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D2: The subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D3: The subject device and predicate devices have differences in Intensity Level for stimulation modes. However, both of subject device and predicate devices have the same indications, frequency, waveform, shape and pulse width. The Maximum Output Voltage and Maximum Output Current of subject device under stimulation modes are equivalent and with the same range as that of the predicate devices.

The heating level of subject device is only one but the Heating temperature range of subject device is within the range of that of the predicate device1(K210756, Neck Care Therapy, model: AST-905H).

Furthermore, the subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests.

Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

The heating temperature range of subject device is within the range of the predicate device1(K210756, Neck Care Therapy, model: AST-905H).

D4: The subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

D5: The timer range of subject device is covered by the range of predicate devices, so the difference doesn't affect the safety and effectiveness of the subject device compared to the predicate device.

D6: The Weight will not affect the safety and effectiveness of the subject device compared to the predicate device.

D7: The dimensions will not affect the safety and effectiveness of the subject device compared to the predicate device.

D8: The Housing Materials and Construction forms the basic construction and ensure the basic safety of device, since the proposed device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests, the difference will not affect the safety of the subject device compared to the predicate device.

D9: There is a small difference in the maximum output voltage for Mode 2 of the subject device compared to the predicate devices. The predicate devices are safe and effective with its output voltage range. Although there is a small difference, the performance testing and electrical safety testing conducted according to ANSI AAMI ES60601-1 and IEC 60601-2-10 for the subject device has demonstrated that the subject device is as safe and effective as the predicate device. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D10: There is a small difference in the output current of Mode 2 of the subject device compared to the predicate devices. The predicate devices are safe and effective with its output current range. Although there is a small difference, the performance testing and electrical safety testing conducted according to ANSI AAMI ES60601-1 and IEC 60601-2-10 for the subject device has demonstrated that the subject device is as safe and effective with its output current as the predicate device. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D11: The small difference in Maximum Phase Charge between the subject device and predicate devices are acceptable and the subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D12: The proposed device has a small difference in maximum current density than the predicate devices. The subject device has also demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests.

Therefore, the difference does not raise the issue of product's safety and effectiveness.

D13: There is a small difference in the Maximum Average Power between the subject device and predicate devices. The Maximum Average Power Density of the subject device is greater than predicate device 1 (Neck Care Therapy, model AST-905H) and smaller than the predicate device 2 (K172897, Neck Care Therapy, 905B), at the same time the Maximum Average Power Density of subject device is less than 0.25 Watts/cm^2.
Furthermore, the subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D14: The difference regarding Burst Mode between the subject device and predicate devices are acceptable given that the subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D15: The difference in the ON Time between the subject device and predicate devices is acceptable given that the subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D16: The difference in the OFF Time between the subject device and predicate devices is acceptable given that the subject device has demonstrated electrical safety by passing ANSI AAMI ES60601-1 and IEC 60601-2-10 tests. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D17: There are differences in the Operating Environment between the subject device and predicate devices. However, the subject device and predicate devices are comply with ANSI AAMI ES60601- 1:2005/(R)2012 and A1:2012, ANSI AAMI IEC 60601-1-2:2014, ANSI AAMI HA 60601-1-11:2015 and IEC 60601-2-10 Edition 2.1 2016-04. Therefore, the differences don’t raise the issue of product's safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, ANSI AAMI HA 60601-1-11 and for safety, IEC 60601-1-2 for electromagnetic compatibility, ISO 10993-5 and ISO 10993-10 for material biological compatibility, IEC 60601-2-10 for performance and IEC 62304 are complied, and see below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
ANSI AAMI IEC 60601-1-2:2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
ANSI AAMI HA 60601-1-11:2015	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

IEC 60601-2-10 Edition 2.1 2016-04	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

The Output Waveform test was performed for the subject device in accordance with Guidance Document for Powered Muscle Stimulator 510(k)s.

8. Discussion of Clinical Accuracy Testing Performed

FUTURE determined that bench and non-clinical testing were sufficient to demonstrate that Transcutaneous Electrical Nerve Stimulator, model: ST-304 is as safe and effective as the predicate device.

9. Conclusions

The electrical safety, EMC, biocompatibility, software verification and validation, basic unit characteristics, and output specifications information provided is sufficient to demonstrate substantial equivalence to the predicate devices. As the Transcutaneous Electrical Nerve Stimulator, model: ST-304 is nearly identical to the predicate devices, differences in their characteristics do not raise any raise new questions regarding safety and effectiveness with identical indications for use and essentially identical technological characteristics, the Transcutaneous Electrical Nerve Stimulator, model: ST-304 is substantially equivalent to the predicate devices.