July 19, 2023

Nu-Beca & Maxcellent Co.
% Diana Sung, MS
Assistant Manager of Regulatory Department
TaiDoc Technology Corporation
B1-7F, No.127, Wugong 2nd Rd.
New Taipei City, Wugu District 24888
Taiwan

Re: K223151
Trade/Device Name: nu-beca Transcutaneous Electrical Nerve Stimulation
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 19, 2023
Received: July 19, 2023

Dear Diana Sung:

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,

Robert Kang -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223151

Device Name
nu-beca Transcutaneous Electrical Nerve Stimulation

Indications for Use *(Describe)*
The nu-beca Transcutaneous Electrical Nerve Stimulation is indicated for temporary relief of pain associated with sore and aching muscles in the lower back and upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with the requirements of 21 CFR 807.92, this summary is being provided to serve as the basis for the substantial equivalence determination.

1. Regulatory Consultant:

Company Name	TaiDoc Technology Corporation
Address	B1-7F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, Taiwan 24888
Contact Person	Diana Sung
Title	Assistant Manager of Regulatory Department
Phone	886-2-6625-8188 #1158
E-mail	Ra.Cert.Groupone@taidoc.com.tw

2. 510(k) Owner Information:

Company Name	Nu-Beca & Maxcellent Co.
Address	3F-1, No. 45, Dexing W. Rd., Taipei, Taiwan, 111046.
Contact Person	David Tsai
Title	President
Phone	886-2-2836-3617 #6000
E-mail	david.tsai@nu-beca.com
Date Prepared	September 30, 2022

3. Candidate Device Information:

Proprietary Name	nu-beca Transcutaneous Electrical Nerve Stimulation
Common Name	Transcutaneous Electrical Nerve Stimulation
Product Code	NUH
Review Panel	Neurology
Classification	2
Regulation Number	21 CFR §882.5890

4. Predicate device Information

Proprietary Name	HIVOX OTC Electrical Stimulator
Mode Name	FT610-B
Manufacturer	HIVOX BIOTEK INC.
Product Code	NUH
510(k) Number	K211403
Review Panel	Neurology
Classification	2
Regulation Number	21 CFR §882.5890

5. Reference Device

Proprietary Name	Cur Model 1
Mode Name	Mode A (Default Mode)
Manufacturer	Thimble Bioelectronics
Product Code	NUH, NGX
510(k) Number	K160052
Review Panel	Neurology
Classification	2
Regulation Number	21 CFR §882.5890

6. Intended Use

The nu-beca Transcutaneous Electrical Nerve Stimulation is indicated for temporary relief of pain associated with sore and aching muscles in the lower back and upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

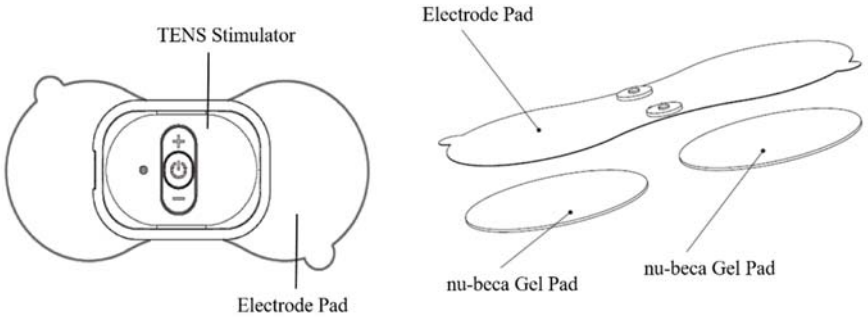
7. Intended Use Population

The nu-beca Transcutaneous Electrical Nerve Stimulation is indicated for different patient populations and is intended for use in Adults Only (22 years of age and older).

8. Device Description

The nu-beca Transcutaneous Electrical Nerve Stimulation consists of following components and accessories:

Components	Functions	Surface Material
TENS Stimulator	The main unit contains buttons and indicators that release adjustable electrical current.	ABS
Electrode Pad	Combine with TENS Stimulator to fix it on user's skin surface.	PET and STEEL
nu-beca Gel Pad	Stick the electrode pad connected with TENS Stimulator on user's skin surface.	ST Gel SR
Charging Cable	Charge the TENS Stimulator.	PVC
Storage Pad	Protect the sticky surface of used nu-beca Gel Pad.	ABS



The nu-beca Transcutaneous Electrical Nerve Stimulation release electrical current with adjustable frequencies and voltages to temporarily relief sore and aching muscles. It has only one model: TN0001. The treatment time for one session use is 15 minutes. User can operate the nu-beca Transcutaneous Electrical Nerve Stimulation by following use interfaces.

Battery charging

The TENS stimulator is charged by inserting the charging cable into USB charging port, and then plugging the adaptor connected with charging cable into electrical outlet.

Assembling

The TENS stimulator, electrode pad and nu-beca Gel Pad should be assembled before application. The nu-beca Gel Pad is stick on the electrode pad to fix the electrode pad in conjunction with TENS stimulator on skin surface. The TENS stimulator is connected with electrode pad by magnet.

Application

Apply the assembled nu-beca Transcutaneous Electrical Nerve Stimulation on pain associated sites: lower back, upper and lower extremities (arm and/or leg).

Operation

The TENS stimulator is switched-on and switched-off by long pressing the power button. The 13 frequencies of electrical current are configured into mode 1 to mode 6. User can adjust the 6 modes by short pressing the power button. There are 1 to 10 adjustable intensity levels, which represent 10 levels of output voltage. User can adjust level 1 to level 10 of intensity by pressing the "+" button to increase the output voltage or pressing "–" button to decrease the output voltage.

Indicator light display

The TENS stimulator displays indicator lights in green and/or orange color under different conditions.

Green light shows under following conditions:

- The TENS stimulator is switched-on.
- The battery is fully charged.

Twinkling green light flashes under following conditions:

- The intensity level is adjusted to the maximum or minimum level.

Twinkling green and orange light flashes under following conditions:

- The electrode pad is not adhered firmly on skin surface.

Twinkling orange light flashes under following conditions:

- The TENS stimulator is charging.
- The electricity is about to deplete.

No light shown: The TENS stimulator is switched-off.

9. Principle of Operation

The nu-beca Transcutaneous Electrical Nerve Stimulation device can generate small pulses of electrical current. Delivered these pulses pass through the skin and activated underlying nerves.

The nu-beca Transcutaneous Electrical Nerve Stimulation outputs electrical pulses to specific nerves via gel pad fixed on the intact skin of lower back, upper and lower extremities and powered by rechargeable lithium battery. The purpose is to temporarily relief the pain associated with sore and aching muscles.

The BOOST circuit controls the voltage amplitude by modifying the Pulse Width Modulation (PWM) circuit while the user pressed the "+" or "–" button to adjust the voltage from 1 to 10 intensities. The frequency of output voltage is controlled by modifying the frequency of Pulse Width Modulation (PWM) circuit while the user short pressed the power button to select the 1 to 6 mode, which consists of different frequency combinations.

10. Comparison to Predicate device

10.1 Intended Use Comparison

The intended use of the nu-beca Transcutaneous Electrical Nerve Stimulation is the same as the predicate device, it is for temporary relief of pain associated with sore and aching muscles in the lower back and upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

10.2 Technological Comparison

The nu-beca Transcutaneous Electrical Nerve Stimulation is substantially equivalent to the predicate device in terms of technological characteristics, including their use environment and function.

Table 1. Summary of intended use and basic characteristics compared to predicate device and reference device

Characteristic	Predicate Device K211403 HIVOX OTC Electric Stimulator	Reference Device K160052 Cur Model 1, Mode A (Default Mode)	Candidate Device K223151 nu-beca Transcutaneous Electrical Nerve Stimulation	Remark
Intended use	The FT610-B is designed for symptomatic relief and management of chronic pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities and lower extremities due to strain from exercise or normal household work activities. It is also indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication. In addition, it also provides a heat function intended to temporarily relieve minor aches and pains.	A transcutaneous electrical nerve stimulation (TENS) Mode which is indicated for the symptomatic relief and management of chronic intractable pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities, and A powered muscle stimulation (PMS) mode which is indicated to improve and facilitate muscle performance in healthy muscles. The CUR Model 1 should be applied to normal, healthy, dry and clean skin of adult patients.	The nu-beca Transcutaneous Electrical Nerve Stimulation is indicated for temporary relief of pain associated with sore and aching muscles in the lower back and upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.	Refer to #D1
Classification	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	Same
Product code	NUH	NUH, NGX	NUH	Same
Type of use	OTC	OTC	OTC	Same
EMC	IEC 60601-1-2 Edition 4.0	IEC 60601-1-2	IEC 60601-1-2: 2014	Same
Electrical safety	ANSI/AAMI ES60601-1:2015/(R)2012 IEC 60601-1-11 Edition 2.0 IEC 60601-2-10 Edition 2.1	IEC 60601-1 IEC 60601-2-10	IEC 60601-1: 2012 IEC 60601-2-10: 2016 IEC 60601-1-11: 2015	Same
Dimension	113 mm x 70 mm x 9.7 mm	36mm x 36mm x 8.5mm	60.5 mm x 44 mm x 11.4 mm	Refer to #D2
Operation environment	10 ºC ~ 40 ºC, 30% ~ 85% R.H.	Not publicly available	5ºC ~ 40 ºC (41 ºF~104 ºF), 15% ~ 90% R.H.	Refer to #D3
Storage environment	-10 ºC ~ 50 ºC, 10% ~ 95% R.H.	Not publicly available	-25 ºC ~ 70 ºC (-13 ºF~158 ºF), 10% ~ 90% R.H.	
Transport environment	-10 ºC ~ 50ºC, 35% ~ 85% R.H.	Not publicly available	-25 ºC ~ 70 ºC (-13 ºF~158 ºF), 10% ~ 90% R.H.	
Power supply	Lithium battery 3V	3.7V Lithium-Polymer battery (rechargeable)	Lithium battery 3.7 V	Refer to #D4
Treatment time	20 minutes fixed	60 minutes	15 minutes fixed	Refer to #D5
Indicator light display	No	Yes	Yes	Refer to #D6

Table 2. Summary of technological characteristics compared to predicate device and reference device

Parameter		Predicate Device K211403 HIVOX OTC Electric Stimulator	Reference Device K160052 Cur Model 1, Mode A (Default Mode)	Candidate Device K223151 nu-beca Transcutaneous Electrical Nerve Stimulation	Remark
Waveform		Symmetrical Biphasic	Biphasic, Asymmetrical	Asymmetrical Biphasic	Similar to K160052 Refer to #D7
Shape		Rectangular	Rectangular	Rectangular	
Maximum Output Voltage	@500Ω	72 ±10% V	42.6V	35.0 V	Similar to K160052 Refer to #D8
	@2KΩ	112 ±10% V	85.2V	55.0 V	
	@10KΩ	120 ±10% V	87.0V	70.0 V	
Maximum Output Current	@500Ω	144 ±10% mA	85.1 mA	75.0 mA	
	@2KΩ	56 ±10% mA	43.1 mA	27.5 mA	
	@10KΩ	12 ±10% mA	8.8 mA	7.0 mA	
Pulse Duration		100 µSec	91.7 usec	100 µSec	Same
Frequency		100 Hz	40-130 Hz	2.0 Hz	Similar to K160052 Refer to #D9
				4.0 Hz	
				5.0 Hz	
				6.0 Hz	
				8.0 Hz	
				10.0 Hz	
				16.0 Hz	
				20.0 Hz	
				32.0 Hz	
				40.0 Hz	
				50.0 Hz	
				64.0 Hz	
				80.0 Hz	
Net Charge per pulse	@500Ω	Not publicly available	7.16uC	7.50 µC	Similar to K160052 Refer to #D10
Maximum Charge	@500Ω	7.2 µC	7.16uC	7.50 µC	Refer to #D11
Maximum Current Density	@500Ω	0.364 mA/cm^2, r.m.s.	0.35 mA/cm^2	1.77 mA/cm^2, r.m.s.	Refer to #D12
Maximum Average Power Density	@500Ω	0.00185 W/cm^2	1.50 mW/cm^2	0.062 W/cm^2	
Burst Mode	Pulse per burst	N/A	N/A	N/A	Same
	Burst per second	N/A	N/A	N/A	
	Burst duration	N/A	N/A	N/A	
	Duty Cycle	N/A	N/A	N/A	

11. Discussion of Differences

10.1 **#D1 (Intended use)**

The intended use of candidate device is different from predicate device due to the following reasons:

- The predicate device can be applied on shoulder and neck.
- The predicate device is indicated for dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.
- The predicate device has the heat function.

The claimed intended use of candidate device is narrower than predicate device, and the electrical safety of candidate device has passed IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-2-10:2016, which demonstrated that the different intended use doesn't affect safety and effectiveness of candidate device.

10.2 **#D2 (Dimension)**

The performance tests verified the claimed specifications of electrical current between candidate device and predicate device. All test results met acceptance criteria, which demonstrated that the different dimension of candidate device meet the intended use, and doesn't affect safety and effectiveness.

10.3 **#D3 (Operation, storage and transportation conditions)**

The storage, transportation and operation environment of candidate device has been verified to comply with the requirements of IEC 60601-1-11:2015.

According to the test results, the basic safety and performance of candidate device were maintained under transport and storage condition and under operation condition, which demonstrated that the different operation, storage and transportation conditions of candidate device meet the intended use, and doesn't affect safety and effectiveness.

10.4 **#D4 (Power source)**

The candidate device uses Lithium battery 3.7V as power source. For predicate device, Lithium battery 3V is used as power source. The electromagnetic compatibility and electrical safety of candidate device has been verified to comply IEC 60601-1-2:2014 and IEC 60601-1:2012. All test results met acceptance criteria, which demonstrated that the different power source of candidate device meet the intended use, and doesn't affect safety and effectiveness.

10.5 **#D5 (Treatment time)**

Although the treatment time is different from the predicate device, the treatment time 15 minutes (automatically switch-off in 15 minutes) of candidate device was verified in software validation tests. All test results met acceptance criteria, which demonstrated that the different treatment time of candidate device meet the intended use, and doesn't affect safety and effectiveness.

10.6 **#D6 (Indicator light display)**

The candidate device displays indicator lights in green and/or orange color under different conditions. For the predicate device, there is no indicator light. The software validation tests were performed to verify the indicator lights correctly display under each state of device, and the EMC and safety test were performed to verify the electromagnetic compatibility and electrical safety of candidate device. All test results met acceptance criteria, which demonstrated that the design of indicator lights of candidate device meet the intended use, and doesn't affect safety and effectiveness.

10.7 **#D7 (Output waveform and shape)**

The candidate device outputs asymmetrical biphasic and rectangular waveform, and the predicate device outputs symmetrical biphasic and rectangular waveform. The candidate device has demonstrated the electrical safety by passing IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-2-10:2016, therefore, the different output waveform shape will not affect the electrical safety of the candidate device.

We have found 510(k) cleared reference device K160052 has identical waveform and shape with the candidate device, which demonstrate that the design of waveform and shape on the candidate device doesn't impact safety and effectiveness.

10.8 **#D8 (Maximum output voltage and Maximum output current)**

The maximum output voltage and maximum output current under 500Ω, 2KΩ and 10KΩ resistance of candidate device are different from predicate device due to different design. The performance test was conducted to verify the maximum output voltage and maximum output current of candidate device under the acceptance criteria followed IEC 60601-2-10:2016, section 201.12.1.102.

The candidate device has also demonstrated the electrical safety by passing IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-2-10:2016, therefore, the different output waveform shape will not affect the electrical safety of the candidate device.

We have found 510(k) cleared reference device K160052 has similar maximum output voltage and maximum output current with the candidate device, which demonstrate that the design of candidate device doesn't impact safety and effectiveness.

10.9 **#D9 (Frequency and Output current)**

The frequencies (2-80Hz) of electrical current generated from candidate device are configured into 6 modes. For predicate device, there is only one mode with fixed frequency 100 Hz. The candidate device has demonstrated the electrical safety by passing IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-2-10:2016, therefore, the different frequency range will not affect the electrical safety of the candidate device.

We have found 510(k) cleared reference device K160052 has 40-130 Hz frequency range similar to 2-80 Hz of candidate device, which demonstrate that the frequency design of candidate device doesn't impact safety and effectiveness.

10.10 **#D10 (Net charge per pulse)**

The candidate device has demonstrated the electrical safety by passing IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-2-10:2016. It can be concluded that the net charge per pulse design of candidate device doesn't affect the safety and effectiveness.

We have found 510(k) cleared reference device K160052 has 7.16μC net charge similar to 7.5μC of candidate device, which demonstrate that the net charge per pulse design of candidate device doesn't impact safety and effectiveness.

10.11 **#D11 (Maximum charge)**

The 7.5μC maximum charge under 500Ω resistance of candidate device is similar to 7.2μC of predicate device. The performance test was conducted to verify the maximum charge of candidate device under the acceptance criteria followed IEC 60601-2-10:2016, section 201.12.1.102. The EMC and safety test were performed to verify the electromagnetic compatibility and electrical safety of candidate device. All test results were within acceptance criteria, which demonstrated that the candidate device with similar maximum charge can meet the intended use, and doesn't affect the safety and effectiveness.

10.12 **#D12 (Maximum current density and Maximum average power density)**

The maximum current density and maximum average power density under 500Ω resistance of candidate device are different from predicate device due to different design.

According to FDA Guidance Document for Powered Muscle Stimulator 510(k)s, page 16, section 3: "*Maximum current density and power density values should be calculated using the conductive surface area of the smallest electrodes provided/recommended for use with the unit; sample calculations should be provided. The maximum power density should be based on the maximum duty cycle and should be averaged over an output duration of one second. The maximum power density should be less than 0.25 Watts/cm^2 to reduce the risk of thermal burns."*, the maximum average power density less than 0.25 Watts/cm^2 under maximum current density is safe, which demonstrated that the 0.062 Watts/cm^2 maximum average power density of candidate device under 1.77 mA/cm^2, r.m.s. maximum current density is within safe range. It can be concluded that the different maximum current density and maximum average power density of candidate device doesn't affect safety and effectiveness.

12. Non-Clinical Testing Summary

11.1 Performance test

The electric current specifications of candidate device were verified by bench tests.

11.1.1 Waveform and shape

The waveform and shape were verified for the candidate device. All test results were demonstrated to meet the acceptance criteria.

11.1.2 Pulse duration

The pulse duration was verified for the candidate device to ensure the electrical pulse of candidate device was outputted within the claimed time interval. All test results were within acceptance criteria, which demonstrate that the pulse duration of candidate device is the same to predicate device and doesn't affect the safety and effectiveness.

11.1.3 Net charge per pulse

The net charge per pulse was verified for the candidate device. All test results were demonstrated to meet the acceptance criteria, which demonstrate that the net charge per pulse of candidate device doesn't affect the safety and effectiveness.

11.1.4 Maximum average power density

The maximum average power density was verified for the candidate device to ensure the maximum energy (Watt) transmitted to the user skin surface for each square centimeter is below the maximum level 0.25 Watts/cm^2 in accordance with FDA Guidance Document for Powered Muscle Stimulator 510(k)s, page 16. Section 3.

All test results were within acceptance criteria, which demonstrated that the maximum average power density of candidate device is within safe range and doesn't affect the safety and effectiveness.

11.1.5 Intensity verification

The output voltage of intensity level was verified for candidate to ensure the output voltage of candidate device meet IEC 60601-2-10:2016. All test results were within acceptance criteria, which demonstrate that each intensity level of candidate device output voltage doesn't affect the safety and effectiveness.

11.1.6 Frequency and output current verification

The frequency and output current were verified for candidate device. All test results were demonstrated to meet the acceptance criteria followed IEC 60601-2-10:2016.

11.2 Biocompatibility

The nu-beca Gel Pad contacts the skin surface of users. The following biocompatibility test were conducted for of patient-contacting material ST Gel SR:

- The cytotoxicity test was performed in accordance with ISO 10993-5:2009.
- The sensitization test was performed in accordance with ISO 10993-10:2021
- The irritation test was performed in accordance with ISO 10993-23:2021

11.3 Storage stability test

Storage stability test of nu-beca Transcutaneous Electrical Nerve Stimulation is performed to ensure the safety and effectiveness are suitable for use over the shelf life of device.

Nonclinical tests were performed in accordance with 21 CFR §882.5890.
Clinical Testing is not applicable. Risks are analyzed to confirm that all identified risks were effectively mitigated. There were no special concerns of safety and effectiveness identified.

13. Conclusions

According to results of nonclinical tests, the **nu-beca Transcutaneous Electrical Nerve Stimulation** has a substantially equivalent safety and effectiveness profile to the predicate device (K211403) and reference device (K160052).