October 10, 2023

NeuroTrigger
Nikolai Kuincher
CEO
Nirim 3
Tel Aviv, Israel 67060
Israel

Re: K223027
Trade/Device Name: NeuroTrigger Basic (NTB)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: September 23, 2022
Received: September 29, 2022

Dear Nikolai Kuincher:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jitendra V. Virani -S

CDR Jitendra Virani
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)*
K223027

Device Name
NeuroTrigger basic (NTB)

Indications for Use *(Describe)*
Device Name: NeuroTrigger Basic

INDICATION FOR USE:
NeuroTrigger Basic is indicated for the prevention or retardation of disuse atrophy, muscle re-education, and for maintaining or increasing range of motion.

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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510K Summary

Submitter:

Submitter's Name	NeuroTrigger LTD
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Contact Person Name:	Nikolai Kunicher, PhD
Title:	CEO
Phone Number:	+972-522963130
Dated:	September 27, 2023

Submitted Device:

Proprietary Name: NeuroTrigger Basic (NTB)

Common or Usual Name: Stimulator, power, muscle

Classification Name: Powered Muscle Stimulator

Product Code: IPF

Device Class: II

Review Panel: Physical Medicine

Regulation Number: 21 CFR 890.5850

Predicate Device: Shenzhen XFT-2000 (K193275)

Device Description:

The NeuroTrigger Basic (NTB) powered muscle stimulator is composed of a hardware component encased in Acrylonitrile Butadiene Styrene (ABS) plastic that attaches to the body with double-sided tape (DST) and delivers electrical stimulation to different body regions through a single use/disposable pre-gelled Y-shaped electrode. The Y-shaped electrodes consist of a PET base, with silver/silver chloride conductive ink, covered by a double coated medical polyethylene DST film, and hydrogel circles at the center of the Y heads.

The NTB System is made up of the following components and accessories:

Main components:

- Stimulator
- Electrodes
- Android app

Accessories:

- Stimulator holder, with double-sided adhesive stickers
- Charging cradle
- USB-C charge cable
- AC/DC Charger

The NTB stimulator contains embedded software that controls the generation of the stimulation signals, provides current measurement circuitry to monitor the delivered current, provides a Bluetooth Low Energy (BLE) wireless communication with remote control SW running on Android based App. The electrical stimulation is delivered to different body regions through the 2 electrode sizes (either wide or narrow span electrodes). The stimulator is stored in the NTB charging cradle, the housing case for the device, when not in use. Both components (the stimulator and the cradle) are made of ABS, but the NTB stimulator contains a PCB board and a lithium battery, and fits into the cradle by magnetized coupling and is held in place with pogo pins. The cradle acts as a charging station for the stimulator in addition to being a housing storage unit. The cradle, built of two parts, contains magnets that allow for the single axis magnetic opening and closure of the case.

The AC/DC charger connects to the cradle through the USB C cable during charging cycles, which is when the stimulator is not in use.

The stimulator holder is supplied to allow for different body region uses, and is also made from ABS material and can be attached to different bodily regions with DST. The cradle and stimulator display different indications (i.e. BLE pairing, charging, connection state, battery status) through LED lights.

NTB user setup is performed under the guidance and instruction of a supervising physician and is controlled wirelessly from the Android smartphone-based mobile application (Bluetooth connection to the stimulator). The stimulator contains embedded software that generates controllable stimulation signal for stimulating nerves and muscles. The stimulation signal parameters can be controlled by special application over Bluetooth Low Energy (BLE) connection. Communication with the stimulator host application is done over BLE, data are encrypted with the standard BLE pairing and encryption/decryption that is done at the BLE level.

The SW is a remote control application installed on portable Android device with support to BLE 4.2 and above to control the HW and serve as UI. Secured login mechanism is implemented on the application to prevent unsecured using of the application also to protect patient's personal information and details

The application supports three types of users:

- Patients
- Clinicians
- Administrators

The SW is programmed to show the following LEDs/Display indications for general functions:

- On/off
- Low power
- Effective electrode contact coupling
- Application coupling

Indications for Use:

NeuroTrigger Basic is indicated for the prevention or retardation of disuse atrophy and muscle re-education to maintain or increase range of motion.

Predicate Comparison Tables

Table 1: Basic Unit Characteristics (comparison with predicate device)

Device Name	NeuroTriggerBasic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
K number	K223027	K193275	
Manufacturer	NeuroTrigger	Shenzhen XFT Medical Ltd.	
Model number	NT-11	XFT-2000	
Product code	IPF	IPF, GZJ	Same
Classification Name/Regulation number	21 CFR 890.5850	21 CFR 890.5850	Same
Intended Use	A powered muscle stimulator intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affect body area.	A powered muscle stimulator intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affect body area.	Same

Device Name	NeuroTriggerBasic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Indications for Use	NeuroTrigger Basic is indicated for the prevention or retardation of disuse atrophy and muscle re-education to maintain or increase range of motion.	XFT-2000 is intended for the following use: - Relaxation of muscle spasms - **Prevention or retardation of disuse atrophy** - Increasing local blood circulation **- Muscle re-education** - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis - **Maintaining or increasing range of motion** - Adjunctive treatment in the management of post-surgical and post-traumatic acute pain.	Substantially equivalent
Technology	Electrical Muscle Stimulation (EMS)	Electrical Muscle Stimulation (EMS)	Same
Power Source - **method of line current isolation**	N/A (battery operated)	N/A (battery operated)	Same
Battery - **Number** - **Size** - **Type**	One rechargeable Lithium, Prismatic, 4.2V (3.7 nominal), 120 milliampere hour (mAh) - 1 battery in stimulator - 31 x 12 mm, 4.95 mm thick - LiPol 4.2 V Lithium ion battery	3 AAA batteries	Substantially equivalent

Device Name	NeuroTriggerBasic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
- Patient leakage current - **Normal condition** - **Single fault condition**	- <1.4 µA - <1.4 µA	- N/A - N/A	Although no data is available for the predicate device, the leakage current is similar or lower than that of other cleared similar devices, so this does not introduce any new safety concerns. In addition, the leakage current meets FDA guidance requirements. Note that this parameter is not applicable to device effectiveness.
Average DC current through electrodes when device is on but no pulses are being applied	0 µA	0 µA	Same
Number of output modes	- 1 mode for neuromuscular stimulation (NMES)	1 mode for NMES - *1 mode for transcutaneous electrical nervestimulation (TENS)*	Substantially equivalent
Programs	• Unlimited number of programs can be created by the user • Frequency, pulse duration, amplitude, ramp up time, and time on/offcan be adjusted	• 10 pre-set NMES programs • 3 pre-set TENS programs • User can create and save custom programs • Frequency, pulse duration, amplitude, treatment time, and time on/off can be adjusted	Substantially equivalent

Device Name	NeuroTriggerBasic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Number of output channels - **synchronous or alternating** - **method of channel isolation**	1 channel - N/A	2 channels - Both - Transistor	Substantially equivalent
Regulated current or voltage	Constant current (also referred to as regulated current)	Regulated current	Same
Software / Firmware/ MicroprocessorControl?	Yes, software and firmware	Yes	Same
Automatic overload trip?	Yes, if a zero load is connected, current shuts off	Yes	Same
Automatic no-load trip?	Yes, if no load is connected, current shuts off	Yes	Same
Automatic shut off	Yes	Yes	Same
User override control?	Yes	Yes, pause button	Same

Device Name	NeuroTriggerBasic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Indicator Display: - **On / Off Status** - **Low Battery?** - **Voltage / Current Level?**	 - Yes - Yes - Yes	 - Yes - Yes - Yes	Same
Timer Range (min) (NMES mode)	Open Stimulation period	60 min	Different. The NTB IFU contains the following Caution statement: "The NeuroTrigger Basic device should be used for a maximum duration of 120 minutes per session. Longer use of the device could lead to skin irritation, burning, or other effects related to overstimulation." Other neuromuscular stimulation devices within product code IPF that are cleared for use by patients at home have a similar maximum duration of use, including the Shoulder Pacemaker (K220994).
Compliance with voluntary standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 ISO 10993-1 Part 1	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Same

Device Name	NeuroTriggerBasic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Compliance with 21 CFR 898?	Yes	Yes	Same
Weight	11.9 g	96 g	Substantially equivalent
Dimensions (mm)	65 x 60 x 13	114 x 66 x 20	Substantially equivalent
Housing material	ABS, injection molding	Silicone & ABS	Substantially equivalent

Table 2: Output Specifications

Device Name	NeuroTrigger Basic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Waveform and shape	Pulsed, symmetric, balance biphasic, rectangular, with interphase interval	Pulsed, symmetric, balanced Biphasic, Rectangular	Same
Area of electrode(s) **Dimensions of electrode(s)**	1.5 cm^2 1.4 cm diameter (round)	19.6 cm^2 5 cm diameter (round)	Different, but does not raise new questions of safety or effectiveness. See discussion below.
Maximum output voltage @ 500 Ω ± 10%	12.5 V	29.7 V	Different, but does not raise new questions of safety or effectiveness. See discussion below.
@ 2 kΩ ± 10 %	50 V	89.1 V	
@ 10 kΩ ± 10%	90 V (maximum voltage remains constant at a load larger than 3.6 kΩ)	125 V	
Maximum output current @ 500 Ω ± 10 %	25 mA	59.4 mA	Different, but does not raise new questions of safety or effectiveness. See discussion below.
@ 2 kΩ ± 10%	25 mA	44.5 mA	
@ 10 kΩ ± 10%	9 mA	12.5 mA	

Device Name	NeuroTrigger Basic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Maximum Phase Charge			Substantially equivalent The calculation of the maximum phase charge of the predicate device was based on the maximum phase duration and the maximum current amplitude delivered into the corresponding load
@ 500 Ω	15.0 µC	10.8 µC	
@ 2 kΩ	15.0 µC	15.6 µC	
@ 10kΩ	5.4 µC	4.4 µC	
Pulse (phase) width	80 - 600 µs	100 - 350 µs	Different, but does not raise new questions of safety or effectiveness. Although the maximum phase duration of the subject device is longer that the predicate, there are other stimulators using a longer phase duration. For example, Sonicator Plus (K071137) uses a max phase duration of 500 µs.
Frequency (Hz)	10 – 300 Hz	100-350 Hz	Substantially equivalent
Net Charge (µCper pulse) (If zero, state method of achieving zero net charge	Zero Biphasic, charge balanced stimulation	Zero Biphasic, charge balanced stimulation	Same

Device Name	NeuroTrigger Basic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Maximum Power Density, (W/cm²) (using smallest electrode conductive surface area)	19.1 mW/cm^2 @ 500Ohm	8.9 mW/cm^2 @ 500Ohm	Different, but does not raise new questions of safety or effectiveness. Per FDA Guidance the maximum power density should be less than 25 mW/cm^2
Max current (RMS) (mA) @ 500 Ω	7.57	16.9	Different, but does not raise new questions of safety or effectiveness. The maximum RMS current is lower in the subject device than the predicate device. RMS value is simply a combination of current amplitude, pulse width, pulse frequency, and burst duty cycle. The RMS value by itself doesn't define the physiological response, and the stimulation parameters are addressed in the discussion below. Thus the difference in the RMS value does not raise new effectiveness concerns.

Device Name	NeuroTrigger Basic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Burst Mode (i.e.,pulse trains) **a) Pulses per burst** **b) Bursts per second** **c) Burst duration (seconds)** **d) Duty Cycle[Line (b) x Line (c)]**	a) 10 - 300 pulses b) 0.09 – 0.32 Hz c) 0.1 – 1.0 s d) Duty cycle:0.9% - 32%	a) 1 - 625 pulses b) 0.05 – 0.5 Hz c) 1 - 5 s d) Not available	Different, but does not raise new questions of safety or effectiveness. There is some overlap between the ranges of the subject and the predicate device. Also, the NTB burst mode parameters are effectively a derivative of the time on and time off parameters listed in the next two lines of this table. • Burst duration is ON Time. • Pulses per burst are calculated as ON Time multiplied by the pulse frequency. • Burst per seconds is calculated as an inverse of ON Time + OFF time. Both ON Time and OFF Time ranges comply with the FDA Guidance for Powered Muscle Stimulators.

Device Name	NeuroTrigger Basic (Device Under Review)	Shenzhen XFT-2000 (Predicate Device)	Comparison
Connectivity	Bluetooth Low Energy (BLE 5.2) connectivity to Android platform-based app	N/A	Different, but does not raise new questions of safety or effectiveness. Many neurostimulators use BLE connectivity to communicate between the stimulator and a custom app (e.g. VitalStim K153224 and PowerDot K210938), so this feature does not raise new questions of safety or effectiveness.

Discussion of Differences in Stimulation Output Specifications

In terms of individual stimulation parameters, the area of the NTB electrodes, the maximum output voltage, maximum output current, and duty cycle are lower than the predicate device, while the maximum frequency is higher with the NTB device. The impact of these stimulation output specifications on comparability of the NTB to the XFT-2000 device and on the safety and effectiveness of the NTB device are discussed below.

- Safety
    - Each of the stimulation output specifications of the subject device that differs from the predicate device (with the exception of the phase width) is lower than that of the predicate, thus they do not present safety concerns.
    - The maximum phase width of the subject device is higher than the predicate. Safety-wise, longer phase duration increases current density and the power density, however the resulting values are still within the safety limits.

- Effectiveness

  While differences in individual output specifications have been noted in Table 14-2 above, to assess the impact of the output specifications on the intended use of the device and how the NTB device compares to the predicate device, one must consider them in combination as it is the combination of these parameters, not the individual parameters themselves, that determines the physiological response to stimulation. It is well-established in neurostimulation that it is possible to achieve the same response of the muscle or nerve using different stimulation parameters. One can adjust the pulse duration, pulse amplitude, pulse frequency and spacing of electrodes to achieve similar muscle contractions with different stimulation parameters.

  An example of the interplay between different stimulation parameters is the strength-duration curve, which is commonly used in electrophysiology. The strength-duration curve shows that the same stimulation effect can be achieved by adjusting either the pulse duration or the pulse amplitude, as long as the delivered electrical charge remains the same. Thus stimulation intensity and the pulse duration should be considered together (as the resulting electrical charge) rather than being analyzed separately.

  The NTB device is capable of delivering similar, and even slightly higher electrical charge as compared to the predicate XFT-2000, therefore the effectiveness of the NTB device is similar to the predicate.

  Specific differences in individual output specifications between the NTB and the predicate XFT-2000 device are discussed below:

    - Maximum voltage at different loads: Since both the subject and the predicate devices are current controlled, the maximum voltage developed by the device does not define the delivered current, and thus the voltage by itself does not impact the effectiveness of the device.
    - Maximum current delivered to the different loads is lower in the NTB than in the predicate device. As mentioned above, the physiological response is dependent on the delivered charge rather than on the maximum value of the current. Thus the maximum value of the delivered current on its own does not affect the effectiveness of the device.
    - The surface area of the subject electrodes is smaller than the predicate electrodes. It is known that smaller surface area electrodes require lower stimulation current to

achieve the same physiological effect. For example, Alon et. al. and Li et. al. demonstrated a linear relationship between the electrode size and the amplitude of the current required to cause the physiological effect.[1,2] In addition, smaller electrodes require smaller spacing between them (i.e. the spacing between the stimulating and the return electrode), thus causing a larger gradient of the electrical potential in the tissue. Since the electrical potential is causing the depolarization and the activation of the nerve or muscle cell, smaller electrodes' spacing is an additional factor which allows the subject device to elicit the same physiological response with lower stimulation current.

- Duty Cycle defines the ratio between the time duration when the stimulation is applied (muscle contraction) and the time when the stimulation is not applied (muscle relaxation). The full cycle consists of muscle contraction followed by muscle relaxation. The predicate device delivers the cycle duration (stimulation ON time + stimulation OFF time) between 2 sec and 20 sec, while the subject device delivers cycles of 3 sec to 11 sec. Both ranges are sufficient for muscle contraction and subsequent muscle relaxation, not raising new concerns of safety or effectiveness.

In summary, the differences in stimulation output parameters do not introduce any new safety concerns as the output parameters are, in general, lower than the predicate device. Despite the fact that certain stimulation parameters of the NTB are lower than the predicate device, the NTB can still effectively activate muscles because the ability to activate muscles is more dependent on the combination of stimulation parameters and electrode placement rather than individual stimulation parameters. Thus, it can be concluded that the set of the stimulation parameters of the subject device is substantially equivalent to that of the predicate device.

Discussion on the non-clinical testing performed

Performance testing was performed to assure safety and effectiveness of the NeuroTrigger Basic device. All necessary bench testing was conducted on the NeuroTrigger Basic device to ensure conformance to design specifications and to support a determination of substantial equivalence to the predicate device. [807.92(b)(1)] The nonclinical, bench testing performed included:

- Biocompatibility testing: The NTB device components that come in direct contact with patient intact skin were tested. Cytotoxicity, sensitization, and irritation testing were performed to establish that the device is safe and effective for human use on intact skin.
    - Cytotoxicity: the NTB device was tested according to ISO 10993-5, and passed successfully demonstrating that it is non-cytotoxic
    - Sensitization: NTB device tested according to ISO 10993-10 and passed. The device does not cause skin sensitization
    - Irritation: NTB device tested according to ISO 10993-23 and passed. The Device is nonirritant.
- Packaging, shelf life, and transit simulation testing were tested on the NTB device, which included the following tests:
    - Shipment simulation test: the NTB device underwent shipment simulation testing following the ASTM D4332-14 and ASTM D4169-16 standards.
    - Accelerated Aging 1 yr: After passing the shipment simulation test, the device

[1] Alon G., Kantor G., Ho. H. Effects of electrode size on basic excitatory responses and on skeletal stimulus parameters. Journal of Orthopaedic & Sports Physical Therapy. Volume 20 Number 1 July 1994.

[2] Li P., Chai G., Zhu K., Lan N., Sui X. Effects of electrode size and spacing on sensory modalities in the phantom thumb perception area for the forearm amputees. Annu Int Conf IEEE Eng Med Biol Soc, 2015:3383-6.

underwent accelerated aging for 1 year following the ASTM F1980-16 standard.

  - Device performance: NTB was tested after passing the 1 yr accelerated aging period and performed according to device requirements. Device is safe and effective for patient use after 1 year aging.

- Performance testing. NTB device was tested prior and post environmental and aging testing to ensure that the device performs according to its design specifications and is safe and effective for use post shelving for at least 1 year. The performance testing can be divided into the following categories:
  - Mechanical (including device assembly)
  - Electrical
  - Functional; and
  - Usability
- Software verification and validation testing was conducted to test for the safe and secure use of the software with the NTB device, which included Bluetooth connection, stimulation parameter identification, and cybersecurity protection. Device function performs as expected and according to software requirements.
- Electrical safety and EMC testing. The NTB device was tested according to the EN60601-1 & IEC60601-1-2 standards for EMC and electrical safety and passed. Furthermore, the device complies with FCC regulation 47CRF15, Section 15.247. The device is safe for patient use.

CONCLUSION:

The NeuroTrigger Basic device is substantially equivalent to the predicate device Shenzhen XFT-2000 (K193275). Both the subject device and the predicate device use electrodes to deliver stimulation to patients' muscles.

The stimulation parameters of NTB are similar to the predicate device. The comparison of the device under review, and the predicate device can be seen in the tables above (Table 1 and Table 2). The NTB device is designed to comply with relevant safety recognized consensus standards. Detailed and strictly controlled testing has been carried out.

Furthermore, tests results and risk analysis show that the NeuroTrigger Basic is a safe for the intended use, and differences between the NTB and the predicate device do not raise any new questions of safety or effectiveness.

These data support that the NeuroTrigger Basic device is substantially equivalent to the predicate device.