September 23, 2020

Shenzhen XFT Medical Limited
% Yoyo Chen
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue,
Xili Town
Shenzhen, 518100 Cn

Re: K193276
Trade/Device Name: Nerve and Muscle Stimulator
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: September 3, 2020
Received: September 9, 2020

Dear Yoyo Chen:

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,

Vivek Pinto, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Nerve and Muscle Stimulator

Indications for Use *(Describe)*
Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of walking, the Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle reeducation, and maintained or increased joint 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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510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1. Administrative Information

Submission Date	September 3 ,2020
Manufacturer information	Submitter's Name: Shenzhen XFT Medical Limited Address: Room 203, Building 1, Biomedicine Innovations Industrial Park #14 Jinhui Road, Pingshan New District Shenzhen Guangdong, CHINA 518118 Contact person: Ms. Julia Ye TEL:+86(0755) 29888818 FAX: +86(0755) 28312625 E-Mail: xftrs2@xft.cn; xfthr1@xft.cn;
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Ms. Yoyo Chen, Mr. Field Fu E-Mail: yoyo@cefda.com; field@cefda.com
Establishment registration number	3004438577

2. Device Information

Type of 510(k) Submission:	Traditional
Common name of the device:	Nerve and Muscle Stimulator
Trade name of the device:	Foot Drop System
Type/Model of the device:	XFT-2001E and XFT-2001EA
Classification name:	Stimulator, Neuromuscular, External Functional；
Review Panel:	Neurology
Device Class	II
Regulation Number	21 CFR 882.5810

3. Predicate Device

Manufacturer	Shenzhen XFT Medical Limited
Trade name	Foot Drop System
Model	XFT-2001D
510(K) Number:	K162718
Product Code	GZI

4. Device Description

Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) is a wearable and DC 3.7V rechargeable lithium battery powered multifunction device, and integrated metal (stainless-steel) electrodes, offering Functional Electrical Stimulation (FES) in device. It can be attached to the leg just below the knee, near the head of the fibula. During a gait cycle, the Nerve and Muscle Stimulator stimulates the common peroneal nerve via metal electrode, which innervates the tibialis anterior and other muscles that cause dorsiflexion of the ankle.

The Nerve and Muscle Stimulator is a microprocessor-controlled device, and uses a smart phone operating application (APP) to store device, user and configuration information via Bluetooth. it can be operated by both smart phone application and the control panel of the device.

Nerve and Muscle Stimulator has 3 working mode, Walk Mode, Training Mode and Evaluation Mode. The walk mode and training mode which can give certain electrical pulses through metal electrode to the proposed area of the leg where the Nerve and Muscle Stimulator are placed. There is no electrical stimulation in the evaluation mode, it is intended to collect the tilt angle data generated by the Stimulator during the patient's walking, and can calculate the recommend parameters based on the collected data.

The control panel of the device has the operating elements of ON/OFF touch button, OLED display, mode selection touch button, intensity touch button and USB port for battery charging. The OLED display can show battery power, selected mode, current intensity and indication of a pause.

The stimulator will connect the APP via Bluetooth, user can set the parameters, mode selection, and intensity adjustment of the stimulation by APP. Logout of the APP or disconnect the Bluetooth, the stimulator can continue to work.

5. Intended Use/Indication for Use

Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of walking, the Nerve and Muscle

Stimulator (Model: XFT-2001E, XFT-2001EA) electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle reeducation, and maintained or increased joint range of motion.

6. Comparison with predicate device

The Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) is substantially equivalent to the predicate device (K162718). This conclusion is based upon comparison on intended use, technological characteristics, output mode and applicable safety standards. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.

Items	New Device (K193726) XFT-2001E and XFT-2001EA	Predicate Device (K162718) XFT-2001D	Comparison
Product code	GZI	GZI	Same
Regulation number	21 CFR 882.5810	21 CFR 882.5810	Same
Device class	2	2	Same
Manufacturer	Shenzhen XFT Medical Limited	Shenzhen XFT Medical Limited	Same
Intended use	Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of walking, the Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle reeducation,	XFT-2001D Foot Drop System is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of walking, the XFT-2001D, electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle reeducation, and maintained or increased joint range of motion.	Same

Items	New Device (K193726) XFT-2001E and XFT-2001EA	Predicate Device (K162718) XFT-2001D	Comparison
	and maintained or increased joint range of motion.		
Patient Population	Adult	Adult	Same
Power source	DC 3.7V, 450mAh, rechargeable lithium battery	DC 3.7V, 400mAh, rechargeable lithium battery	Different (Note1)
-Method of Line Current Isolation	Type BF	Type BF	Same
-Patient Leakage Current (mA): -Normal condition - Single fault condition	 Normal condition: 0.5mA Single fault condition: 2mA	 Normal condition: 0.5mA Single fault condition: 2mA	Same
Number of Output Modes	3 modes: Walk Mode, Training Mode and Evaluation Mode: • There are 2 modes under walk mode- Smart mode and Normal mode; • There are 10 modes under training mode- 9 preset modes and 1 customize mode.	2 modes: Gait Mode and Training Mode: • There are 3 modes under gait mode-Smart mode, Normal mode and Gait Analysis; • There are 10 modes under training mode- 9 preset modes and 1 customized mode.	Different (Note2)
Number of Output Channels	1	1	Same
Waveform	Asymmetrical Biphasic	Asymmetrical Biphasic	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (volts) (+/- 10%)	45V@500 Ω 90V@1K Ω 156V@2K Ω 158V@10K Ω	45V@500 Ω 90V@1K Ω 156V@2K Ω 158V@10K Ω	Same

Items	New Device (K193726) XFT-2001E and XFT-2001EA	Predicate Device (K162718) XFT-2001D	Comparison
Maximum Output Current (mA) (+/- 10%)	15.58mA rms @500 Ω 13.51mA rms @ 2 kΩ 2.73mA rms @ 10 kΩ	14mA rms @500 Ω 11mA rms @ 2 kΩ 2.2mA rms @ 10 kΩ	Different (Note3)
Duration of primary (depolarizing) phase (μ sec)	Unknown	Unknown	Same
Pulse Duration (μ sec) (+/- 10%)	100~300 μ sec Pulse width adjustable in following discrete steps:100/150/200/250/300 μ sec	100~300 μ sec Pulse width adjustable in following discrete steps:100/150/200/250/300 μ sec	Same
Frequency (Hz) (+/- 10%)	16~50 Hz Frequency adjustable in following discrete steps: 16/ 20/ 25/ 33/ 40 / 50Hz	16~33Hz Frequency adjustable in following discrete steps: 16/ 20/ 25/ 33Hz	Different (Note3)
For interferential modes only: -Beat Frequency (Hz)	Unknown	Unknown	Same
For multiphasic waveforms only: -Symmetrical phases? -Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	No symmetrical phase	No symmetrical phase	Same
Net Charge (microcoulombs (μC) per pulse)	0μC@500 Ω	0μC@500 Ω	Same
Maximum Phase Charge, (μC) ±10%	27μC @500Ω 23.4μC @2kΩ 4.74μC @10kΩ	27μC @500Ω 23.4μC @2kΩ 4.74μC @10kΩ	Same

Items		New Device (K193726) XFT-2001E and XFT-2001EA	Predicate Device (K162718) XFT-2001D	Comparison
Maximum Current Density (mA/cm², r.m.s.) ±10%		0.53mA/cm² @500Ω 0.46mA/cm² @2kΩ 0.09mA/cm² @10kΩ	0.7mA/cm² @500Ω 0.58mA/cm² @2kΩ 0.11mA/cm² @10kΩ	Different (Note3)
Maximum Average Current (average absolute value), mA±10%		15.58mA @500Ω 13.51mA @2kΩ 2.73mA @10kΩ	12.66mA @500Ω 10.97mA @2kΩ 2.22mA @10kΩ	Different (Note3)
Maximum Average Power Density, (W/cm²)		0.008W/cm² @500Ω 0.025 W/cm² @2KΩ 0.005 W/cm² @10KΩ	0.005W/cm²@500 Ω 0.014W/cm²@2KΩ 0.003W/cm²@2KΩ	Different (Note3)
Burst Mode	(a) Pulses per burst	Burst length and PPS dependent	Burst length and PPS dependent	Same
	(b) Bursts per second	Depends on duration times and interval times	Depends on duration times and interval times	
	(c) Burst duration (seconds)	1 to 5 sec in 0.1 sec steps Depends on duration times and interval times	1 to 5 sec in 0.1 sec steps Depends on duration times and interval times	
	(d) Duty Cycle: Line (b) x Line (c)	unknow	unknow	
Indicator Display	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	
	Voltage/Current Level?	Yes	Yes	
Duration Time /ON time (Seconds)		1-5 sec in 0.1 sec steps	1-5 sec in 0.1 sec steps	Same
Interval Time /OFF time (Seconds)		1-10 sec in 0.1 sec steps	1-10 sec in 0.1 sec steps	Same
Timer Range (Minutes)		20 minutes	20 minutes	Same
Stimulation Trigger Source		Tilt sensor	Tilt sensor	Same

Items	New Device (K193726) XFT-2001E and XFT-2001EA	Predicate Device (K162718) XFT-2001D	Comparison
Anatomical Sites	Limb	Limb	Same
Shipping and Storage	Temp:-20°C to 55°C Relative Humidity ≤93% Atmos: 70-106KPa	Temp:-20°C to 55°C Relative Humidity ≤93% Atmos: 70-106KPa	Same
Operating Conditions	Temp:5°C to 40°C Relative Humidity ≤80% Atmos: 86-106KPa	Temp:5°C to 40°C Relative Humidity ≤80% Atmos: 86-106KPa	Same
Electrode Size and Shape	Rectangular 1(29.32*18.04mm), Rectangular 2(28.26*18.38mm), Rectangular 3(29.01*17.89mm), Rectangular 4(89.00*32.80mm)	5 cm diameter Round	Different (Note4)
Electrode materials	Stainless steel SUS 316L	Hydrogel/conductive fabrics	Different (Note4)
Materials-Cuff	TPE (Thermoplastic Elastomer)	Fabric	Different (Note5)
Maximum Stimulation Period	5 seconds	5 seconds	Same
Wireless Communication	Blue tooth 4.0	Blue tooth 4.0	Same
Wireless Control	Smart phone application	Remote control	Different (Note 6)
Weight	XFT-2001E:155g; XFT-2001EA: 140g	43g	Different (Note7)
Dimensions (mm) [W x H x D]	XFT-2001E: 126.8 x102.4 x15.5mm; XFT-2001EA: 122.8 x104.8 x15.9mm	73*70*10mm	Different (Note7)

Items	New Device (K193726) XFT-2001E and XFT-2001EA	Predicate Device (K162718) XFT-2001D	Comparison
Housing Materials and Construction	ABS	ABS	Same
Expected Service Life	5 years	5 years	Same
Compliance with 21 CFR 898?	Yes	Yes	Same
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Same

Note1: Power source

The difference between the subject device and predicate device for power source is the capacity of rechargeable lithium battery. However, the battery is complied with IEC 62133-2:2017 standard requirements, and the subject devices have passed the IEC 60601-1 test standard. Therefore, the difference between the subject and predicate devices do not impact safety and effectiveness.

Note 2: Number of Output Modes

Based on the performance testing in comparison with the predicate device under different loads, it is concluded that the difference does not raise any safety or effectiveness issues.

Note 3: Maximum Output Current, Frequency, Maximum Current Density, Maximum Average Current, Maximum Average Power Density

Although the above parameters of subject device are different with the predicate device, but these parameters are within the acceptable range by comparison with the device which previously cleared. Therefore, the difference between the subject and predicate devices do not impact safety and effectiveness.

Note 4: Electrode Size, Shape and Electrode materials

Although the electrode is different with predicate device, however, the tests for biocompatibility, durability and electrical safety test are all carried out to ensure the device could be safe and effective during normal use. Therefore, it is considered that the difference between the subject and predicate devices does not impact safety and effectiveness.

Note 5: Materials-Cuff

Even though the electrode and cuff material of subject devices are is different with Predicate Device, but they all passes biocompatibility test in according to ISO 10993-5 and ISO 10993-10 standards. Therefore, these differences do not impact safety and effectiveness.

Note 6: Wireless Control

Although the wireless control of subject device is different with predicate device, but they all meet the requirements of wireless coexistence. Based on the performance test result of wireless coexistence, the quality of wireless could be assured during normal use. Therefore, the difference does not raise any safety or effectiveness issues.

Note 7: Weight and Dimensions

After comparison with the previously declared device, we believe that the weight of subject device could be safe and effective during normal use for this type of device. Regarding the dimension of subject device, it could be adjusted during normal use to accommodate the leg circumferences of intended population, and ensure the device could be fit during normal use. Therefore, the difference does not raise any safety or effectiveness issues.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The proposed device Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) has passed safety testing in according to following standards.

1) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).
2) 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
3) IEC 60601-1-11:2015 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
4) IEC 60601-2-10:2012+AM1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
5) ANSI/IEEE C63.27:2017 American National Standard for Evaluation of Wireless Coexistence
6) FCC Rules and Regulations, Part 15, Subpart C and Subpart B

The rechargeable lithium battery has passed the IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.

The power adapter has passed the ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

7.2. Biocompatibility Test

The proposed device Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) has passed biocompatibility tests in according to following standards:

1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

7.3. Performance Testing-Bench

The proposed device Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) has conducted and passed performance testing in according to FDA guidance-*Guidance for Industry, FDA Reviewer/Staff and Compliance-Guidance Document for Powered Muscle Stimulator 510(k)s, document issued on June 9, 1999.*

8. Clinical Test Data

Substantial equivalence does not depend on the clinical test data.

9. Conclusion

The Nerve and Muscle Stimulator (Model: XFT-2001E, XFT-2001EA) is substantially equivalent to the predicate device (K162718). This conclusion is based upon comparison on intended use, technological characteristics, output mode and applicable safety standards. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.