November 30, 2017

Shenzhen XFT Medical Limited
Mrs. Jiang Xiaoying
Manager
RM 203, BLD1, 14 Jinhui Road, New District
Shenzhen, Guangdong CN

Re: K162718
Trade/Device Name: Foot Drop System, Model 2001-D
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: October 27, 2017
Received: October 31, 2017

Dear Mrs. Xiaoying:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162718

Device Name
Foot Drop System (Model XFT-2001D)

Indications for Use *(Describe)*
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 re-education, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 30, 2017
Submitter:	Shenzhen XFT Medical Limited Room203, Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan New District, Shenzhen, China
Contact Person:	Mrs. Jiang Xiaoying xfthr3@xft.cn Tel: +86-(0) 755-29888818
Device: Trade Name:	Foot Drop System
Model:	XFT-2001D series
Classification Names:	External Neuromuscular Functional Stimulator
Product Code:	GZI
Regulation Number:	21 CFR 882.5810
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device(s):	K123972

Device Description:	Nerve and Muscle Stimulator (Foot Drop System) is a battery-operated, electrical stimulator that can be used for functional electrical stimulation (FES). Nerve and Muscle Stimulator (Foot Drop System) is an external functional electrical stimulator. It is a small device that attaches to the leg just below the knee, near the head of the fibula. During a gait cycle, Nerve and Muscle Stimulator (Foot Drop System) stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that cause dorsiflexion of the ankle. The Nerve and Muscle Stimulator (Foot Drop System) consists of the Patient Kit and the Clinician Kit. The Patient Kit comprises of all the components and accessories that the patient will take home and use. The Clinician System includes the Medical Records Management Software.
Intended Use:	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 re-education, and maintained or increased joint range of motion.
Technology:	Proposed device and predicate device use a small electrical signal to stimulate the nerves in the leg, causing the muscles contract and produce a movement that can help walking. The most common use of FES is as a treatment for foot drop where disruptions in the nerve pathways between the legs and brain which means the front of your foot cannot be lifted to the correct angle when walking. The Foot Drop System employs the same fundamental scientific technology as its predicate devices.

Basis for Substantial Equivalence:	Technological characteristics, features, specifications, materials and intended uses of the new device are substantially equivalent to the quoted predicated device. The parameters such as waveform, frequency, pulse width, output current and voltage, although not exactly identical to this particular predicate, do not raise any new questions of safety or effectiveness. Applicable performance and safety testing was performed to verify technological and functional characteristics including any design modification. The differences that exist between the devices are insignificant in terms of safety and effectiveness. The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.

Table 1 Comparison between XFT-2001D and the predicate device

Specification	Predicate Device	Proposed device
K number	K123972	K162718
Device name	WalkAide	XFT-2001D
Manufacturer	Innovative Neurotronics, Inc.	Shenzhen XFT Medical Limited
Intended Use/ Indications for Use	The Innovative Neurotronics WalkAide 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 gait, the WalkAide electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.	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 re-education, and maintained or increased joint range of motion.
Contraindications	Do not use on persons with implanted demand type cardiac pacemakers or defibrillators. Do not place the electrodes in the carotid sinus region (throat). Laryngeal or pharyngeal spasms placed across the throat or in the mouth. Do not place the electrodes over malignant tumors. Do not place the electrodes over areas in which symptoms of existing thrombosis are present. Do not use if person has a history of seizure disorder.	Do not use on persons with implanted demand type cardiac pacemakers or defibrillators Do not place the electrodes in the carotid Sinus region (throat). Laryngeal or pharyngeal spasms may occur when the electrodes are placed across the throat or in the mouth. Do not place the electrodes over malignant tumors. Do not place the electrodes over areas in which symptoms of existing thrombosis are present. Do not use if person has a history of seizure disorder.
Patient Population	Adult	Adult
Power Source(s)	1.5 AA Battery (not rechargeable)	DC3.7V, 400mAh, rechargeable lithium battery (Stim Unit & Remote control)
Patient Leakage Current	-Normal condition: 0.5mA -Single fault condition: 2mA	-Normal condition: 0.5mA -Single fault condition: 2mA

Specification	Predicate Device	Proposed Device
Number of Output Modes	2 modes: gait mode and training mode	2 modes: gait mode and training mode
Number of Output Channels	1	1
Regulated Current or Regulated Voltage	Voltage	Current
Software/Firmware/Microprocessor	Microprocessor	Microprocessor
Auto Overload Trip?	No	No
Auto No-Load Trip?	No	Yes
Auto Shut Off?	No	Yes
Patient Override Control?	Yes	Yes
Indicator Display On/Off Status? Low Battery? Voltage/Current Level?	 Yes Yes Yes	 Yes Yes Yes
Timer Range (minutes)	30 minutes	20 minutes
ON Time (seconds)	1-5 sec in 1 sec steps	1-5 sec in 0.5 sec steps
OFF Time (seconds)	1-10 sec in 1 sec steps	2-10 sec in 1 sec steps
Net Charge (µC per pulse)	16.7-33Hz	16.7-33Hz
Frequency (Pulses per second)	25-300 microseconds Pules width adjustable in following discrete steps: 25/50/100/150/200/250/300µS	100-300 µS Pules width adjustable in following discrete steps:100/150/200/250/300uS
Pulse width	25-300 microseconds Pules width adjustable in following discrete steps: 25/50/100/150/200/250/300µS	100-300 µS Pules width adjustable in following discrete steps: 100/150/200/250/300uS
Max Phase Charge(µC)	41.2µC @ 500 ohm 28µC @ 1K ohm	27.0µC @ 500 ohm 27.0µC @ 1K ohm
Max Current Density, (mA/cm²)	1.8mA/cm² (500 ohm)	0.7mA/cm² (500 ohm)
Maximum Power Density, (W/cm²)	0.0128W/cm² (500 ohm)	0.005W/cm² (500 ohm)

Specification	Predicate Device	Proposed Device
Max Output Voltage	unknown@ 500 ohm	45V @ 500 ohm
	121V@ 1 K ohm	90V @ 1 K ohm
	unknown @ 2 K ohm	156V @ 2 K ohm
	unknown @ 10 K ohm	158V@ 10 K ohm
Max Output Current	20.7mA rms@ 500 ohm	14mA rms@ 500 ohm
	unknown @ 2 K ohm	11mA rms@ 2 K ohm
	unknown @ 10 K ohm	2.2mA rms@10 K ohm
Burst Mode -Pulses per burst -Bursts per second -Burst duration (seconds) -Duty Cycle [Line (b) x Line (c)]	Burst length and PPS dependent Depends on ON and OFF times 1 to 5 sec in 1 sec steps Depends on ON and OFF times	Burst length and PPS dependent Depends on ON and OFF times 1 to 5 sec in 1 sec steps Depends on ON and OFF times
Stimulation Trigger Source	Tilt Sensor or Foot Sensor	Tilt Sensor
Anatomical Sites	Limb	Limb
Shipping and storage	Temp: -20 °C to 60 °C Relative Humidity: 95% max, non-condensing	temp: -20°C to 55°C Relative Humidity< 93% Atmos.: 700-1060hPa
Operating Conditions	Temp: 0-40 degrees C Altitude: from -400 to 2,400 meters (- 1300 to 8,000 ft) Relative Humidity: 0 to 95%, non-condensing	temp: -5°C to 40°C Relative Humidity< 80% Atmos.: 860-1060hPa
Electrode Size and Shape	3.175 cm (1.25 inches) diameter Round	5 cm diameter Round
Electrode materials(Basic mechanical element) Material contacting skin	Hydrogel and Stainless Steel (SS)316	Hydrogel /conductive fabric
Materials-cuff	fabric	fabric

Specification	Predicate Device	Proposed Device
Maximum Stimulation Period	3 seconds	3 seconds
Wireless communication	Blue tooth 1.2	Blue tooth 4.0
Weight	87.9 g	43 g
Dimensions (in.) [W x H x D]	82*61*21mm	73*70*10mm
Housing Materials and Construction	ABS	ABS
Waveform	Asymmetrical Biphasic	Asymmetrical Biphasic
Shape	rectangular	rectangular
Expected Service Life	5 years	5 years
Compliance with 21 CFR 898?	Yes	Yes
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

Performance Data: The following performance data were provided in support of the substantial equivalence determination.

EMC and Electrical safety

Electrical safety and EMC testing were conducted on the XFT-2001D (clinical kit), consisting of a Cuff, a Functional Stimulation Unit, and a Remote Control.
The device complies with 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. IEC 60601-1:2005 （ Third Edition）+CORR.1:2006+CORR.2:2007+A1:2012 Consolidated version Medical electrical equipment -Part 1: General requirements for basic safety and essential performance.

IEC 60601-2-10:2012 Medical electrical equipment -Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

Biocompatibility

The electrode pads are the mainly body contacting parts. Electrode pads, as accessories of the device, are adopted the Self-adhesive Electrode manufactured by Top Rank Health Care Equipment Co., Ltd and have been cleared by FDA in November 22, 2013 as K132588.The electrode pads is considered skin contacting for a duration of less than 24 hours.

The biocompatibility evaluation for the XFT-2001D cuff was conducted in accordance with ISO 10993-5:2009 Biological evaluation of medical devices

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

Software Verification and Validation

The software for this device was considered as a “MODERATE” level of concern, the software failure or design flaw prior to mitigation may lead to an error in the intensity or timing of stimulation that could result in minor injury such as skin irritation to the patient. And software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Conclusion: Shenzhen XFT Medical Limited believes that the XFT-2001D Foot Drop System is as safe and effective, and performs in a substantially equivalent manner to the predicate device. The modifications do not raise any safety or effectiveness issues and meet the applicable requirements of lEC60601-2- 10 "Particular requirements for the safety of nerve and muscle stimulators." and the FDA document "Guidance Document for Powered Muscle Stimulator 510(k)s" June 9, 1999. We conclude that the proposed XFT- 2001D Foot Drop System is substantially equivalent to the WalkAide System (K123972).