November 5, 2021

Guangzhou Longest Science & Technology CO., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou Keda Biological Tech Co., Ltd.
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Guangzhou, Guangdong 510060
China

Re: K202110
Trade/Device Name: MStim Drop Model: LGT-233
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: October 5, 2021
Received: October 6, 2021

Dear Jet Li:

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,

Amber Ballard, PhD
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)*
K202110

Device Name
MStim Drop Model: LGT-233

Indications for Use *(Describe)*
The MStim Drop LGT-233 is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. The device electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.
The MStim Drop LGT-233 may also:
•Prevent/retard disuse atrophy
•Maintain or increase joint range of motion
•Increase local blood flow

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
510K number: K202110

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. **Date of the summary prepared: November 04, 2021**

2. **Submitter's Information**

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Contact Person: Mr. Jet Li
Tile: Regulation Manager
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3. **Subject Device Information**

Type of 510(k) submission: Traditional
Common Name: External functional neuromuscular stimulator
Trade Name: MStim Drop Model: LGT-233
Classification Name: Stimulator, neuromuscular, external functional; Stimulator, muscle, powered
Review Panel: Neurology, Physical Medicine
Product Code: GZI, IPF

Regulation Number: 882.5810, 890.5850

Regulation Class: 2

4. Predicate Device Information

Sponsor	Bioness Inc	Otto Bock Healthcare Products GmbH
Device Name	L300 Go System	Otto Bock Healthcare Products GmbH
510(k) Number	K162407	K141812
Product Code	GZI, IPF	GZI; GZI
Regulation Number	21 CFR §882.5810 21 CFR §890.5850	21 CFR 882.5850 and 21 CFR 882.5810
Regulation Class	2	2

5. Device Description

The MStim Drop LGT 233 is a wearable foot drop device, which is mainly consists of stimulator main unit, electrode lead wire, electrodes pad, leg bandage and battery charger. The stimulator main unit can be charge by the battery charger.

The device can control the out stimulation and treatment time setting by APP application provided by the manufacturer, and it can trigger and control the pulse stimulation on and off by detecting the swing phase of gait during walking. The device was design to use FES (Functional Electrical Stimulation) to treat and improve the patient s foot drop and help to improve walking ability. It has two modes: Training mode, Walk mode. Training mode is suitable for muscle training when the patient is seated or lying down (patient lacking active training), which can promote muscle recover, prevent muscle atrophy, improve joint range of motion, and increase local blood flow. Walk mode is walking with the electrical stimulation.

6. Intended Use / Indications for Use

The MStim Drop LGT-233 is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. The device electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The MStim Drop LGT-233 may also:

- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion

• Increase local bloodflow

7. Test Summary

The Device has been evaluated the safety and performance by lab bench testing according to the following standards:

1. IEC 60601-1-2: 2014: Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic Compatibility
2. IEC 60601-1:2005: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
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: A1 2016 Medical Electrical Equipment - Part 2: 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. IEC 62133-2: 2017: Secondary cells and batteries containing alkaline or other non-acid electrolytes- Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications- Part 2: Lithium systems
7. Biological evaluation ofmedical device Part 10: Tests for irritation and skin sensitization(ISO 10993-10:2010)
8. Biological evaluation of medical device Part 5: Cytotoxicity test- In vitro method (ISO 10993-5:2009)

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the MStim Drop Model: LGT-233 is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate device do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Device Name and Model	MStim Drop Model: LGT-233	L300 Go System	MyGait Stimulation System	--

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
510 (K) Number	Applying	K162407	K141812	--
Product Code	GZI, IPF	GZI, IPF	GZI, IPF	--
Regulation Number	882.5810, 890.5850	21 CFR § 882.5810 21 CFR § 890.5850	21 CFR 882.5810, 21 CFR § 890.5850	--
Indication for use	The MStim Drop LGT-233 is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. The device electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait. The MStim Drop LGT-233 may also: Prevent/retard disuse atrophy Maintain or increase joint range of motion Increase local blood flow	The L300 Go System is intended to provide ankle dorsiflexion in adult and pediatric individuals with foot drop and/or assist knee flexion or extension in adult individuals with muscle w eakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L300 Go Systemelectrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.	The stimulation system is intended to provide ankle dorsiflexion and knee flexion or extension in individuals with foot drop and thigh muscle weakness following an upper motor neuron injury or disease. During gait, the stimulation system sends electric stimuli to muscles in the affected leg, initiating dorsiflexion of the foot and knee extension or flexion and may thus improve the individual's gait. The stimulation system may also prevent or retard atrophy caused by inactivity, facilitate muscle reeducation, maintain or improve the range of motion in the joints and promote local blood circulation.	SE
Apply parts	Leg	Leg and foot	Leg and foot	SE
Power Sources	Adapter model: HYI11-005 (USA) and HYI11-005 (Europe) Adapter supply voltage: AC 100~240V, 50/60Hz Adapter output: DC 5V, 2A Battery: 3.7V, 1200mAh, lithium battery.	Battery operated	Battery operated	Minor difference Note 1
Indicator display	LED and APP	--	--	Minor difference Note 1

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Method of Line Current Isolation	Battery operated	--	Medical Class II Power Adapter	SE
Number of Modes for Micro current stimulation	2 (For Evaluation mode: no micro current stimulation)	Two modes: Biphasic Symmetric and Biphasic Asymmetric. Applicable to both lower leg and thigh position of the device.	2	SE
Number of Channels for Micro current stimulation	1	Lower leg small cuff – 1 channel; Lower leg regular cuff – 1 or 2 channels (in 2 channel configuration, both channels function as a single channel with separately adjustable medial / lateral stimulation intensity); Thigh cuff – 1 channel	2	SE
Synchronous or Alternating	Not applicable – single channel device	Alternating (at one time only one channel is activated)	Synchronous or alternating	SE
Regulated Current or Regulated Voltage	Regulated Voltage	Current	Regulated Current	SE Note 2

Elements of Comparison		Subject Device	Predicate Device I	Predicate Device II	Remark
Software/Firmware/ Microprocessor control		Yes	Yes	Yes	SE
Automatic Overload Trip		Yes	Yes	Yes	SE
Automatic No- load Trip		Yes.	Yes	Yes	SE
Automatic Shut Off		Yes.	Yes	No	SE
Patient Override Control		Yes	Yes	Yes ON/OFF Button	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	SE
	Low Battery	Yes	Yes	Yes	SE
	Voltage/Current Level	Yes	Yes	No	SE
Timer Range		Treatment time: 1min-60min, stepping 1min; Timer tolerance: ±2%; When finish, the device can stop output and prompt	Max stimulation duration (clinician selectable) Training mode: 5-60 minutes	5 to 120min in steps of 5 min	Minor difference Note 2

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Console weight	60g (only main unit)	Control Unit: 60g, EPG: 60g, Lower leg FSC:150g, Thigh cuff: 300g, Foot Sensor: 25g	78g	SE
Housing Materials and Construction	ABS	Remote Control: Bay State Polymer PA- 2000RX EPG: Bay State Polymer PA-2000RX (Polycarbonate + ABS) Lower Leg FSC: Biocompatible fabric over plastic (POM Hi) skeleton Thigh FSC: TPU Foot Sensor: ABS (Sensor housing), Bay state Polymer PA-2000RX (Electronics housing)	ABS	SE
Waveform	Biphasic square	Biphasic Symmetrical	Biphasic	SE
Shape	Rectangular	Rectangular	Rectangular	SE
Maximum Output Voltage (+/- 10%)	50V ±10% @ 500Ω 90V ±10% @ 1KΩ 120V ±10% @ 2KΩ 130V ±10% @ 10KΩ	Lower leg: 50V@500Ω Thigh: 50V@500Ω Lower leg: 130V@2K Ω Thigh: 130V@2K Ω lower leg: 130V@10K Ω Thigh: 130V@10K Ω	45V +-10% @ 500Ω 90V +-10% @ 1KΩ 120V +-10%@2K Ω n/a @10K Ω (no stimulation possible at 10kΩ)	Minor difference Note 3

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Maximum output Current	100mA ±10% @ 500Ω 90mA ±10% @ 1KΩ 60mA ±10% @ 2KΩ 13mA ±10% @ 10KΩ	Lower leg: 100mA@500Ω Thigh: 100mA@500Ω Lower leg: 65mA@2KΩ Thigh: 65mA@2KΩ Lower leg: 13mA@10KΩ Thigh: 13mA@10KΩ	90mA (+/- 10%) @ 500Ω 90mA (+/- 10%) @ 1KΩ 60mA (+/- 10%)@ 2K Ω n/a @10K Ω (no stimulation possible at 10kΩ)	Minor difference Note 3
Frequency range	10~80Hz	10, 15, 20, 25, 30, 35, 40, 45 Hz	10 to 80Hz in 1Hz steps	Minor difference Note 4
Pulse width range	50~500µs;	100, 150, 200, 250, 300µs (each: positive and phase) Interphase period µs: 50, 100, 200 Total pulse duration: 250, 350, 450, 550, 650 µs (for interphase interval of 50µs)	Symmetrical: 50 ~400µs in steps of 50µs Asymmetrical: pos.: 50 ~ 400µs in steps of 50µs Neg.: 200 ~1600µs in steps of 100µs	Minor difference Note 4
Pulse duration	50~500µs;	Positive phase: 100, 150, 200, 250, 300 µs Negative phase: 100, 150, 200, 250, 300 µs	Symmetrical: 50 ~400µs in steps of 50µs Asymmetrical: pos.: 50 ~ 400µs in steps of 50µs Neg.: 200 ~1600µs in steps of 100µs	Minor difference Note 4

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Net Charge	0uC @ 500Ω	0μC using inverted balanced phases	0μC @ 500Ω Balanced pulses	SE
Maximum Current Density	Train mode: 0.532mA/cm2 @500Ω, Walk mode: 0.53mA/cm2 @500Ω	Maximum current levels are: Lower leg: 16.43 mA (rms) Thigh: 16.43 mA (rms) Maximum current density is: Lower leg (small cuff): 1.63 mA/cm2 (rms), for smallest electrodes area of 10.1 cm2 Lower leg (regular cuff): 1.04 mA/cm2 (rms), for smallest electrodes area of 15.8 cm2 Thigh: 0.23 mA/cm2 (rms), for smallest electrodes area of 72 cm2	1,51 mA/cm2 @500Ω,	Minor difference Note 5
Maximum Power Density	Train mode: 5.66 mW/cm2 @500Ω, Walk mode: 5.62 mW/cm2 @500Ω	Lower leg (small cuff): 13.4 mW/cm2, for smallest Electrodes area of 10.1 cm2 Lower leg (regular cuff): 8.5 mW/cm2, for smallest electrodes area of 15.8 cm2 Thigh: 1.9 mW/cm2, For smallest electrodes area of 72 cm2	0.024 W/cm2	Minor difference Note 5
ON time	For Train mode: 2~40s For Walk mode: N/A	Training mode: 4- 20 sec Gait mode: 1-10 sec (the max stimulation duration after triggering event is detected)	1 to 4 sec in 0.1sec steps	Minor difference Note 6
OFF time	For Train mode: 2.0~60.0s For Walk mode: N/A(As swing phase detecting)	Training mode: 4- 20 sec Gait mode: not limited (As swing phase detecting)	1 to 30 sec in 1sec steps	Minor difference Note 6

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Contraction and Relaxation time	Adjustable, due to different modes.	--	Adjustable, due to different modes.	SE
Environment for operating	Temperature: 5 to 40℃; Rel. humidity: ≤80%;	--	--	SE
Environment for storage and transport	Temperature: -20 to 55℃; Rel. humidity: ≤93%;	--	--	SE
Biocompatibility	Electrode pad and Belt: Compliant with requirements of ISO10993-5, ISO10993- 10, ISO10993-12, standards	--	--	SE
Electrical Safety, EMC	Compliant with requirements of IEC 60601-1, IEC60601-2- 10 , IEC 60601-1-2, IEC 60601-1-11, IEC 62133-2 safety standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, FCC part 15 subpart C and B1	IEC 60601-1:2005 +A1:2012; IEC 60601-1-11:2010; IEC 60601-2-10:2012; IEC 60601-1-2:2007	SE

Comparison in Detail(s):

Note 1 (Power Source(s) and Method of Line Current Isolation):

The power source is only energy source for the operation of the device, it do not affect the output of the micro current. And the device complies with IEC 60601-1 requirements for evaluation of safety. So such minor difference do not raise safety and effectiveness issue.

For display method, even there is minor difference on display design. However it is only for status and setting interface display, and the display APP function and interface had been evaluated in software

validation; So such minor difference do not raise safety and effectiveness issue.

Note 2 (Timer Range):

The design of the timer range is based on the intended use. For MStim Drop Model: LGT-233, the operating time is adjustable by operator according to physician direction. So the timer setting range difference would not impact its safety and effectiveness, comparing predicate devices.

Note 3 (Maximum Output Voltage and Maximum Output Current):

The effect of micro current stimulation is determined by micro-current output waveform and output current. There is only little difference between the output voltage and current of the subject device from the predicated devices, it can still obtain the same effect because our output voltage and output current are in the range which is similar to the value of K162407 and predicate device K 141812. Even the predicate device II have no stimulation at 10K ohm, but its output voltage at 500, 1K and 2 KOhm is similar to subject device; and the predicate device I have similar output voltage as proposed subject device,

Also, the subject device comply with IEC 60601-1, and IEC60601-2-10 for its safety verification, comparing with the predicate devices. Therefore, the minor difference would not affect safety and effectiveness of the subject.

Note 4 (Frequency and Pulse-width):

For Frequency: There is minor difference on frequency of output waveform pulse between subject device and predicate device I, but the frequency means that pulse number in a completed cycle of waveform, the frequency difference means that the pulse numbers difference which deliver to patient body per second. And the frequency of subject device is same to the one of predicate device II (K141812), so its minor difference would not impact the safety and effectiveness of subject device.

For Pulse width: The stimulation time of micro current stimulation is determined by pulse width of micro-current output waveform. Frequency and pulse is the time parameter of the waveform. There is only little difference between the pulse width of the subject device from the predicated device I, it can still obtain the same effect because output current and pulse width is similar to the value of Predicate device II (K141812). Also, the subject device complies with IEC 60601-1, and IEC60601-2- for safety evaluation. Therefore, the minor difference on pulse width would not affect its safety and effectiveness of subject device.

Note 5 (Maximum current density and Maximum power density):

The effect of micro current stimulation is determined by micro-current output pulse width and output current. Even there is only little difference between the value of current density and maximum power density of the subject device and the predicated device due to electrode pad size, but the value of current density and maximum power density of subject device are in the range which is similar to the value K162407. Even the maximum current density and the maximum power density of subject

device is less than predicate device II (K141812), but its value was covered in predicate device I(K162407).

And the maximum power density meet with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Note 6 (On time and OFF time):

On time and OFF time are designed according to the circuit design of the device for max stimulation time. Even there is minor difference for on time and Off time between subject device and predicate device. But for MStim Drop Model: LGT-233, the operating time is adjustable so that the operator can made applicable stimulation time to apply on patient body by adjusting operation time based on physician direction. So the minor difference for On time and Off time between subject device and predicate device would not affect safety and effectiveness of subject device.

Finial Conclusion:

The subject device MStim Drop Model: LGT-233 is Substantial Equivalence to the predicate devices.