March 4, 2020

Bioness Inc.
Shanna Hu
Regulatory Affairs Manager, FES Technology
25103 Rye Canyon Loop
Valencia, California 91355

Re: K200262
Trade/Device Name: L100 Go System
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: January 31, 2020
Received: February 3, 2020

Dear Shanna Hu:

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,

For Vivek Pinto, Ph.D.
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
L100 Go System

Indications for Use *(Describe)*

The L100 Go System is intended to provide ankle dorsiflexion in adults with foot drop or muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L100 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot; thus, it also may improve the adult's gait.

The L100 Go System may also:

- Facilitate muscle re-education
- 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: L100 Go System

Applicant Name: Bioness Inc.

Contact Person(s): Shanna Hu
Regulatory Affairs Manager, FES Technology
Bioness Inc.
25103 Rye Canyon Loop
Valencia, CA 91355, U.S.A
Office Number: (661) 362-6694
Email: shanna.hu@bioness.com

Mercedes Bayani
Global Vice-President, Clinical & Regulatory Affairs
Bioness Inc.
Office Number: (661) 902-5324
Fax Number: (661) 362-4851
Email: mercedes.bayani@bioness.com

Date Prepared: March 4, 2020

Trade Name: L100 Go System

Classification: **Name:** External functional neuromuscular stimulator
Product Code: GZI and IPF
Regulation No: 21 CFR § 882.5810, § 890.5850
Class: II
Classification Panel: Neurology

Establishment Registration No.: 3004553866

Reason for Submission: Device Modifications

Type of Submission: Special 510(k)

Predicate Device:
Company: Bioness, Inc.
Device: L300 Go System, K190285

Purpose of this Special 510(k):

This Special 510(k) is submitted for a system called L100 Go System which is the same device as the Lower Leg configuration of the predicate L300 Go System with modified cuff design. None of the modifications affect the intended use of the device nor do they alter the fundamental scientific technology of the device.

Device Description:

The L100 Go System is designed to improve gait in adults suffering from foot drop or muscle weakness. The L100 Go System can also deliver transcutaneous stimulation to the muscles in the lower leg to facilitate muscle re-education, prevent/retard disuse atrophy, maintain or increase joint range of motion, and/or increase local blood flow.

The L100 Go system consists of the following L300 Go components/accessories with the exception of a modified lower leg cuff:

1) External Pulse Generator (EPG), which can be plugged into Lower Leg Cuff. EPG contains user interface including control and indications. EPG also contains integrated motion sensors enabling detecting gait events.
2) Lower Leg Cuff, including cradle for the EPG. This is the only L300 Go component modified for the L100 Go.
3) Clinician Application (CAPP), installed on tablet PC. CAPP is used by a trained clinician during configuration of the system for optimal fitting to the patient.
4) Power supply (charger) with two USB ports and a proprietary cable to charge the EPG.
5) Tester, which is used for trouble shooting to confirm that stimulation is being delivered.
6) Optional Mobile Application (MAPP), based on the iOS and Android SmartPhone platform enabling the patients to wirelessly control the EPG(s) and retrieve and monitor their daily activity.
7) Electrode and electrode bases which are attached to the inner side of the lower leg cuff.

The L100 Go System can be operated in one of the following modes:

- Gait Mode
- Training Mode
- Clinician Mode

Gait Mode is used for walking, and it can be selected by the clinician and also by the patient. Training Mode is used to train muscles when patients are not walking (for example, sitting or lying down), and it can be selected by either the clinician or the patient. Clinician Mode allows the clinician to apply enhanced training and is only available to the clinicians.

Indications for Use:

The L100 Go System is intended to provide ankle dorsiflexion in adults with foot drop or muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L100 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot; thus, it also may improve the adult's gait.

The L100 Go System may also:

- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

Modifications Addressed in this Special 510(k)

This Special 510(k) addresses the new L100 Go Cuff which is a modification of the predicate L300 Go lower leg cuffs. The L100 Go Cuff combines the design elements of both the L300 Go lower leg Regular and Small cuffs.

Summary of Technological Characteristics

The Table below summarizes the technological characteristics of the subject device in comparison to those of the predicate device, specifically, the lower leg configuration of the predicate device.

	L300 Go System (K190285)	L100 Go System (this submission)	Equivalency Assessment
Manufacturer	Bioness Inc.	Bioness Inc.	Same
510(k) number	K190285	To be assigned_____	N/A
Product code	GZI & IPF	GZI & IPF	Same

Table continues next page

	L300 Go System (K190285)	L100 Go System (this submission)	Equivalency Assessment
Intended use	The L300 Go System is intended to provide ankle dorsiflexion in adult and pediatric individuals with foot drop and/or to assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (*e.g.*, stroke, damage to pathways to the spinal cord). The L300 Go System 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 L300 Go System may also: • Facilitate muscle re-education • Prevent/retard disuse atrophy • Maintain or increase joint range of motion • Increase local blood flow	The L100 Go System is intended to provide ankle dorsiflexion in adults with foot drop or muscle weakness related to upper motor neuron disease/injury (e.g., stroke, damage to pathways to the spinal cord). The L100 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot; thus, it also may improve the adult's gait. The L100 Go System may also: • Facilitate muscle re-education • Prevent/retard disuse atrophy • Maintain or increase joint range of motion • Increase local blood flow	Same (The intended use of L100 Go System is a subset of the predicate device. The L100 Go System is a lower leg cuff only system, therefore, it does not assist knee flexion or extension)
Number of Output Modes	2 modes: Biphasic Asymmetric and Symmetric	2 modes: Biphasic Asymmetric and Symmetric	Same
Number of Programs	• Gait • Training/Exercise • Cycle Training Mode • Clinician mode	• Gait • Training/Exercise • Clinician mode	Different (Cycle Training Mode is disabled for the L100 Go System)
Regulated Current or Regulated Voltage	Current	Current	Same

Table continues next page

	L300 Go System (K190285)	L100 Go System (This submission)	Equivalency Assessment
Power Source	Control Unit: Li Coin Cell, CR2032, 3 V, 240 mAh EPG: Rechargeable, Li-Ion, Prismatic, 3.7 V, 1000 mAh Foot Sensor: Li Coin Cell, CR2032, 3 V, 240 mAh	EPG: Rechargeable, Li-Ion, Prismatic, 3.7 V, 1000 mAh	Same (optional Control Unit and Foot Sensor are not offered with the L100 Go System)
Method of Line Current Isolation	N/A (Battery operated)	N/A (Battery operated)	Same
Patient Leakage Current, Normal condition [µA]	Less than 1.0 (IEC 60601-1)	Less than 1.0 (IEC 60601-1)	Same
Patient Leakage Current, Single fault condition [µA]	3.0 (IEC 60601-1)	3.0 (IEC 60601-1)	Same
Number of Output Modes	Two: Symmetric & Asymmetric	Two: Symmetric & Asymmetric	Same
Number of Output Channels	Small lower leg cuff: 1 Regular lower leg cuff: 1 or 2 Thigh cuff: 1	Lower leg cuff: 1	Same (The L100 Go lower leg cuff has the same output channel as the L300 Go small lower leg cuff)
Synchronous or Alternating?	Alternating (at one time only one channel is activated)	N/A (only one channel will be activated)	Same (L100 Go cuff is single channeled. This is the same as L300 Go small lower leg cuff)
Method of Channel Isolation	Isolation between lower leg and thigh cuff stimulators: Thigh and Lower cuffs are stimulated by different battery operated EPG's without galvanic connection between them. Isolation between channels within the regular lower cuff stimulator: channels in the	Isolation between channels with the lower leg cuff stimulator: N/A (Only one channel will be activated)	Same (The isolation between channels is not applicable to L100 Go lower leg cuff stimulator, this is the same as L300 Go small lower leg cuff stimulator)

	L300 Go System (K190285)	L100 Go System (This submission)	Equivalency Assessment
	same EPG are switched using high voltage FET switches. Isolation between channels within the small lower cuff stimulator: N/A (only one channel will be activated) Isolation between channels within the Thigh cuff stimulator: N/A (only one channel will be activated)		
Regulated Current or Regulated Voltage?	Current	Current	Same
Software/Firmware/Microprocessor-Controlled	Yes	Yes	Same
Automatic Overload Trip?	Yes	Yes	Same
Automatic No-Load Trip?	Yes	Yes	Same
Automatic Shut Off?	Yes	Yes	Same
Patient Override Control?	Yes	Yes	Same
Indicator Display: **• On/Off Status?** **• Low Battery?** **•Voltage/Current Level?**	Yes Yes Yes	Yes Yes Yes	Same
Timer Range [minutes]	No	No	Same

Table continues next page

	L300 Go System (K190285)	L100 Go System (This submission)	Equivalency Assessment
Max Output Current (± 10%)	Lower leg cuffs: 100 mA @ 500 Ohm Thigh cuff: 100 mA @ 500 Ohm	Lower leg cuff: 100 mA @ 500 Ohm	Same (L100 Go lower leg cuff has the same maximum output current as the L300 Go lower leg cuff. Thigh cuff is not available in the L100 Go System)
Max Average Current Density [mA_{RMS}/cm^2] [Over smallest electrode]	Lower leg EPG: small cuff, small round electrodes (36mm) 1.27 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2) Thigh EPG: 0.18mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74 cm^2)	Lower leg EPG: Lower leg cuff, regular round electrodes (45mm) 0.82 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 15.9 cm^2)	Different (since L100 Go cuff only comes in the size same as the predicate regular cuff, the calculation is based on the electrode of the regular cuff. Thigh cuff is not available in the L100 Go System)
Max Average Power Density, (mW/cm^2)	Lower leg EPG: small cuff, small round electrodes (36mm) 8.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2) regular cuff, regular round electrodes (45mm) 5.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 15.9 cm^2) Thigh EPG: 1.1mW/cm^2 (500 Ω, I_{rms}=13.0mA, electrode area of 74 cm^2)	Lower Leg EPG: Lower leg cuff, regular round electrodes (45mm) 5.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 15.9 cm^2)	Same (L100 Go cuff only comes in regular size)

Table continues next page

	L300 Go System (K190285)	L100 Go System (This submission)	Equivalency Assessment
Stimulation Channels	Regular Cuff: 1 or 2 (In 2-channel mode, both function as a single channel but with separately adjustable medial/ lateral stimulation intensity) Small Cuff: 1 Thigh Cuff: 1	Lower leg cuff: 1	Same (L100 Go has one stimulation channel which is identical to channel #1 of L300 Go Regular Cuff)
Frequency/ Phase duration	Frequency: 10, 15, 20, 25, 30, 35, 40, 45 Hz Symmetric and Asymmetric positive: 100, 150, 200, 250, 300µs Asymmetric Negative: 300, 450, 600, 750, 900µs	Frequency: 10, 15, 20, 25, 30, 35, 40, 45 Hz Symmetric and Asymmetric positive: 100, 150, 200, 250, 300µs Asymmetric Negative: 300, 450, 600, 750, 900µs	Same
Electrodes used in the system	Lower Leg Cuffs: • 2 Hydro-Gel electrodes assembled on electrode bases, or • 2 non-woven cloth electrodes assembled on electrode bases, or • 2 non-woven cloth electrodes attached with snaps (also called “QuickFit” electrodes), or • 3 non-woven cloth electrodes attached with snaps (segmented electrodes [also called “steering” electrodes], using common anode to allow separate adjustment of medial and lateral stimulation. This electrode is only used for regular cuff) Thigh Cuff: • 2 single, non-woven cloth electrodes attached with snaps	Lower leg Cuff: • 2 Hydro-Gel electrodes assembled on electrode bases, or • 2 non-woven cloth electrodes assembled on electrode bases, or • 2 non-woven cloth electrodes attached with snaps (also called “QuickFit” electrodes)	Different (L100 Go does not use steering electrodes)

	L300 Go System (K190285)	L100 Go System (This submission)	Equivalency Assessment
Clinician Control/ Programming	Clinician uses the Clinician Programmer (CAPP) to set stimulation energy and temporal parameters related to the functional stimulation performance for dorsiflexion control	Clinician uses the Clinician Programmer (CAPP) to set stimulation energy and temporal parameters related to the functional stimulation performance for dorsiflexion control	Same
Clinician Programmer (CAPP) Platform	Tablet PC	Tablet PC	Same
User Control	Using hand-held Control Unit, the mobile application (MAPP), or the EPG-based interface, the user can: • Turn system On/Off (EPG only) • Start/Stop stimulation • Select Gait/Training program • Fine-tune stimulation intensity around working point set by the clinician • Test L300 Lower Leg EPG & Thigh EPG stimulation before starting to ambulate	Using the mobile application (MAPP), or the EPG-based interface, the user can: • Turn system On/Off (EPG only) • Start/Stop stimulation • Select Gait/Training program • Fine-tune stimulation intensity around working point set by the clinician • Test L100 Lower Leg EPG stimulation before starting to ambulate	Same (Control Unit is optional, and is not offered with the L100 Go System)
Stimulation trigger source (when used for gait)	In gait mode, stimulation is triggered by: (1) the motion sensor embedded in the EPG (two-dimension tilt); or (2) Foot Sensor that detects Heel On & Heel Contact events during gait and transmits them wirelessly to the lower and thigh EPGs.	In gait mode, stimulation is triggered by: (1) the motion sensor embedded in the EPG (two-dimension tilt).	Same (Foot Sensor is optional, and is not offered with the L100 Go System)

Table continues next page

	L300 Go System (190285)	L100 Go System (This submission)	Equivalency Assessment
Communication method	Control Unit – Lower Leg /Thigh EPG: wireless Bluetooth (Low Energy) communication protocol Gait Sensor – Lower Leg/Thigh EPG: wireless Bluetooth (Low Energy) communication protocol Clinician Programmer – EPG: wireless Bluetooth (Low Energy) communication protocol MAPP – Lower Leg /Thigh EPG: wireless Bluetooth (Low Energy) communication protocol	Clinician Programmer – EPG: wireless Bluetooth (Low Energy) communication protocol MAPP – Lower Leg /Thigh EPG: wireless Bluetooth (Low Energy) communication protocol	Same (Control Unit and Foot Sensor are optional, and are not offered with the L300 Go System)
Compliance with Voluntary Standards	Yes. • IEC 60601-1 • IEC 60601-2-10 • IEC 60950-1 • IEC 60601-1-11 • IEC 60601-1-2 FCC part 15:2007 Federal Communications Commission (FCC) regulations Subpart C, 15.247	Yes. • IEC 60601-1 • IEC 60601-2-10 • IEC 60950-1 • IEC 60601-1-11 • IEC 60601-1-2 FCC part 15:2007 Federal Communications Commission (FCC) regulations Subpart C, 15.247	Same
Compliance with 21 CFR 898?	Yes	Yes	Same
Weight	EPG: 60 [gram] Lower leg regular Cuff: 150 [gram] Lower leg small Cuff: 104 [gram]	EPG: 60 [gram] Lower Leg Cuff: 127 [gram]	Different (The L100 Go Cuff is lighter compared to the L300 Go lower regular cuff, this is because the L100 Go cuff does not have the TPU frame)

Table continues next page

	L300 Go System (190285)	L100 Go System (This submission)	Equivalency Assessment
Dimensions [mm] (WxHxD)	EPG: 82x47x15 [mm] Lower leg regular Cuff: 160x100x125 [mm] Lower leg small Cuff: 110x80x100 [mm]	EPG: 82x47x15 [mm] Lower Leg Cuff: 160x100x125 [mm]	Same (The L100 Go cuff has the same dimension as the L300 Go lower regular Cuff)

Table ends here

The difference between the predicate device and the device in this submission is in the number of programs offered, the availability of the optional Control Unit and Foot Sensor, the number of available electrodes, and the weight of the cuff. The subject device is a simpler system, therefore, the Cycle Training Mode feature is disabled. For the same reason, the optional Control Unit and Foot Sensor that are offered with the predicate device is not offered with the subject device. Furthermore, the subject device, the L100 Go System, is a single channel system, therefore, the steering electrode which is used for 2 channel stimulation is not applicable. These technological differences do not affect the safety and effectiveness of the subject device.

Summary of Nonclinical Tests Submitted

The modified cuff design was subjected to verification testing to ensure no loss of mechanical strength and functionality.

Conclusion:

The L100 Go System has been verified and validated successfully for its intended use through the combination of predicate device bench testing and thorough verification and validation testing of all changes. Based on the result of the nonclinical testing, Bioness concludes that the device is substantially equivalent to the predicate L300 Go System.