March 14, 2019

Bioness Inc.
Shanna Hu
Sr. Regulatory Affairs Specialist
25103 Rye Canyon Loop
Valencia, California 91355

Re: K190285
Trade/Device Name: L300 Go System
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: February 8, 2019
Received: February 11, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Kelliann T. Wachrathit -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190285

Device Name
L300 Go System

Indications for Use *(Describe)*
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:
o Facilitate muscle re-education
o Prevent/retard disuse atrophy
o Maintain or increase joint range of motion
o 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: L300 Go System

Applicant Name: Bioness Inc.

Contact Person(s): Shanna Hu
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Date Prepared: February 7, 2019

Trade Name: L300 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, K173682

Purpose of this Special 510(k):

This Special 510(k) is submitted to add an Android version Mobile Application to the L300 Go System as well as to include minor modifications made to the device since the clearance of the last 510K, K173682. None of these changes affect the intended use of the device nor do they alter the fundamental scientific technology of the device.

Device Description:

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 consists of the following components:

1) External Pulse Generator (EPG), which can be plugged into lower leg Functional Stimulation Cuff (FSC) or thigh FSC or into both cuffs. EPG contain user interface including control and indications. EPG also contains integrated motion sensors enabling detecting gait events.
2) Lower leg FSC, including cradle for the EPG.
3) Upper leg FSC, including cradle for the EPG.
4) Clinician Application (CAPP), based on tablet PC. CAPP will be used by a trained clinician during configuration of the system for optimal fitting to the patient.
5) Power supply (charger) with two USB ports and a proprietary cable to charge the EPG.
6) L300 Go Tester.
7) Optional Control Unit that allows simple control of the EPG(s) such as selecting mode of operation (gait/training) or fine-tune the stimulation intensity for each EPG individually.
8) Optional Foot Sensor, which uses a dynamic gait tracking algorithm to detect heel events and wirelessly synchronizes stimulation.
9) Optional Mobile Application (MAPP), which can be downloaded on a smartphone and offers the same control functions as the optional Control Unit, as well as enabling the patients to retrieve and monitor their daily activity. At the time of clearance of K173682, the MAPP was only an iOS-based application. In this submission, Bioness is adding an Android-based MAPP. The software features, user interface, and wireless communication protocol of the Android version are the same as the iOS version, the only difference is the operating system.

The L300 Go System can be operated in one of the following modes:

- Gait Mode
- Training Mode
- Cycle 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. Cycle Training Mode is used to train muscles while the patient is using a stationary exercise bicycle, 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 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

Modifications Addressed in this Special 510(k)

This Special 510(k) addresses the following modifications:

- Changes in the External Pulse Generator (EPG) software and Firmware.
- Changes in the Mobile Application (MAPP) iOS software.
- Changes in the Clinician Application (CAPP) software.
- Addition of the cycle training mode (software changes only).
- Changes in the EPG bottom enclosure.
- Clinician Kit Packaging Change.
- Labeling Changes.
- Addition of an Android version Mobile Application (MAPP).

Summary of Technological Characteristics

The Table below summarizes the technological characteristics of new device in comparison to those of the predicate device.

	L300 Go System (K173682)	L300 Go System after Design Modifications
Manufacturer	Bioness Inc.	Bioness Inc.
510(k) number	K173682	K190285
Product code	GZI & IPF	GZI & IPF
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 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
Number of Output Modes	2 modes: Biphasic Asymmetric and Symmetric	2 modes: Biphasic Asymmetric and Symmetric
Number of Programs	• Gait • Training/Exercise • Clinician mode	• Gait • Training/Exercise • Cycle Training Mode • Clinician mode
Regulated Current or Regulated Voltage	Current	Current

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	L300 Go System (K173682)		L300 Go System after Design Modifications	
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		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	
Microprocessor-Controlled	Yes		Yes	
Max Output Current (± 10%)	Thigh FSC: 100 mA @ 500 Ohm load	L300 Lower Leg FSC: 100 mA @ 500 Ohm load	Thigh FSC: 100 mA @ 500 Ohm load	L300 Lower Leg FSC: 100 mA @ 500 Ohm load
Max Average Current Density [mA_{RMS}/cm^2] [Over smallest electrode]	Thigh EPG: 0.18 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74 cm^2)	Lower Leg EPG: small cuff, gel electrodes 1.27 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2)	Thigh EPG: 0.18 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74 cm^2)	Lower Leg EPG: small cuff, gel electrodes 1.27 mA_{rms}/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2)
Max Average Power Density, (mW/cm^2)	Thigh EPG: 1.1 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74 cm^2)	Lower Leg EPG: small cuff, gel electrodes 8.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2) regular cuff, gel electrodes 5.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 15.9 cm^2)	Thigh EPG: 1.1 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 74 cm^2)	Lower Leg EPG: small cuff, gel electrodes 8.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 10.2 cm^2) regular cuff, gel electrodes 5.3 mW/cm^2 (500 Ω, I_{rms}=13.0 mA, electrode area of 15.9 cm^2)

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	L300 Go System (K173682)		L300 Go System after Design Modifications	
Stimulation Channels	Thigh EPG: 1	Lower Leg EPG: 2 (functioning as a single channel with separately-adjustable medial / lateral stimulation intensity)	Thigh EPG: 1	Lower Leg EPG: 2 (functioning as a single channel with separately-adjustable medial / lateral stimulation intensity)
Electrodes used in the system	Lower Leg FSC: • 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) Thigh FSC: • 2 single, non-woven cloth electrodes attached with snaps		Lower Leg FSC: • 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) Thigh FSC: • 2 single, non-woven cloth electrodes attached with snaps	
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 and/or knee weakness control		Clinician uses the Clinician Programmer (CAPP) to set stimulation energy and temporal parameters related to the functional stimulation performance for dorsiflexion control and/or knee weakness control	
Clinician Programmer (CAPP) Platform	Tablet PC		Tablet PC	

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	L300 Go System (K173682)	L300 Go System after Design Modifications
User Control	Using hand-held Control Unit, the mobile application (MAPP), or the EPG-based interface, the user can: • Turn system On/Off (via EPG only) and 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 hand-held Control Unit, the mobile application (MAPP), or the EPG-based interface, the user can: • Turn system On/Off (via EPG only) and 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
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)); or (2) Foot Sensor that detects Heel On & Heel Contact events during gait and transmits them wirelessly to the lower and thigh EPGs.
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	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

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Summary of Nonclinical Tests Submitted

Software and Firmware changes were subject to verification testing to ensure no loss of original functionality. Software changes related to the addition of Cyclic Training Mode were subjected to both verification testing and validation testing.

Because of a modification in the bottom enclosure of the External Pulse Generator (EPG), The EPG was retested for Environmental Ingress Protection. The modified EPG successfully passed the test and continue to meet the safety requirements and classification requirement of IP42.

Transportation test were performed to address the new packaging of the Clinician's Kit. The new packaging passed all tests.

Conclusion:

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