March 9, 2018

Bioness, Inc.
Mary Dadone, Ph.D.
25103 Rye Canyon Loop
Valencia, California 91355

Re: K173682
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: November 30, 2017
Received: December 1, 2017

Dear Dr. Dadone:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173682

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:
• 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
Bioness Inc.
L300 Go System

510(k) Summary: L300 Go System

Applicant Name: Bioness Inc.

Contact Person(s): Mary Dadone, Ph.D.
Regulatory Consultant to Bioness Inc.
Office Number: (661) 714-0701
Email: mary.dadone@bioness.com

Mercedes Bayani
Global Director, Regulatory Affairs, Bioness Inc.
Office Number: (661) 902-5324
Fax Number: (661) 362-4851
Email: mercedes.bayani@bioness.com
25103 Rye Canyon Loop
Valencia, CA 91355, U.S.A

Date Prepared: March 8, 2018

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: Traditional 510(k)

Predicate Device:
Company: Bioness, Inc.
Device: L300 Go System
K162407

Purpose of this Traditional 510(k):

This Traditional 510(k) is submitted to clear several minor modifications and to address an upgrade in the Mobile Application (MAPP) for the L300 Go System. 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 assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, spinal cord injury) or other disability. 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).
8) Optional Foot Sensor, which uses a dynamic gait tracking algorithm to detect heel events and wirelessly synchronizes stimulation.
9) Optional Mobile Application (MAPP), based on the SmartPhone platform enabling the patients to wirelessly retrieve and monitor their daily activity. At the time of clearance of K162407, the MAPP did not include any control feature, but control features like those of the Optional Control Unit have been added to the MAPP and are part of this submission.

Indications for Use:

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 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 Traditional 510(k)

This Traditional 510(k) addresses the following modifications:

- Change in the External Pulse Generator (EPG) cover material
- Firmware/Electrical Changes
- Changes in the Clinician Application (CAPP) software
- Changes in the Mobile Application (MAPP) software
- Labeling Changes
- Packaging Changes

Summary of Technological Characteristics

Table 1 below summarizes the technological characteristics of new device in comparison to those of the predicate device. Summary Comparison Table

	L300 Go System (K162407)	L300 Go System after Design Modifications
Manufacturer	Bioness Inc.	Bioness Inc.
510(k) number	K162407	K173682
Product code	GZI & IPF	GZI & IPF

Table 1 continues next page

	L300 Go System (K162407)	L300 Go System after Design Modifications
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 • Clinician mode
Regulated Current or Regulated Voltage	Current	Current

Table 1 continues next page

	L300 Go System (K162407)		**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)

Table 1 continues next page

	L300 Go System (K162407)		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	

Table 1 continues next page

	L300 Go System (K162407)	L300 Go System after Design Modifications
User Control	Using hand-held Control Unit 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; 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; 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

Table 1 ends here

Summary of Nonclinical Tests Submitted

Because of a modification in the assembly process for the optional Control Unit (CU), the CU was retested for Environmental Ingress Protection by Minnetronix Inc. (Bioness development vendor) using a validated test method. The modified CU successfully passed the Environmental Ingress Protection testing.

Because of a change in the Electrical Pulse Generator (EPG) housing material, the EPG was retested for Mechanical Vibration and Shock using a validated Minnetronix test method. The modified EPG successfully passed the Mechanical Vibration and Shock testing.

Packaging and shipping tests were performed to address the new packaging system. These tests included Initial Manual Handling, Vehicle Stacking, Loose Load Vibration, Low Pressure, Vehicle Vibration, Concentrated Impact, and Final Manual Handling (ASTM D5276-98, Schedule A, Level III). All packaging passed all tests.

Software changes were subjected to verification testing to include regression testing to ensure no loss of original functionality. In the version change from MAPP 1.0 to MAPP 2.0, new functions were introduced, and those new functions were subjected to both verification testing (including regression testing) and validation testing. Electrical safety and electromagnetic compatibility testing, including coexistence with common wireless emitters, was completed under the predicate submission and evaluated for applicability to the design modifications proposed under the current submission.

Conclusion:

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