DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 27, 2017

Bioness Inc.
% Evan L. Rosenfeld, M.D., J.D.
Regulatory Consultant
MDJD Consulting
5905 Warm Mist Ln.
Dallas, Texas 75248

Re: K162407
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: December 16, 2016
Received: December 21, 2016

Dear Evan L. Rosenfeld, M.D., J.D.:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

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)*
K162407

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 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.

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510(k) Summary
Bioness Inc.
L300 Go System

510(k) Summary: L300 Go System

Company name: Bioness Inc.

Contact person:

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Global Director, Regulatory Affairs
Bioness Inc.
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25103 Rye Canyon Loop
Valencia, CA 91355, U.S.A.

Application Correspondent:

Evan L. Rosenfeld, M.D., J.D.
Regulatory Consultant for Bioness Inc.
MDJD Consulting
Office Number: (972) 239-7021
Fax Number: (972) 239-7021
Email: evanrosenfeld2@sbcglobal.net

Date prepared: January 27, 2017

Trade Name: L300 Go System

Classification name: External functional neuromuscular stimulator

Class: II

Panel Identification: Neurology

Product code: GZI and IPF

Regulation number:

21 CFR § 882.5810 External functional neuromuscular stimulators

21 CFR § 890.5850 Powered muscle stimulators

Predicate devices:

1. Company: Bioness Neuromodulation Ltd.
   Device: NESS L300 Plus System (K103343)
2. Company: Bioness Neuromodulation Ltd.
   Device: NESS L300 System (K122784)
3. Company: Innovative Neurotronics, Inc.
   Device: WalkAide System (K140886)

Purpose of the traditional 510(k) notice:

The L300 Go System is a new device that is substantially equivalent to its own prior generation devices, the NESS L300 Plus System, the NESS L300 System and the Innovative Neurotronics, Inc. WalkAide System.

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:

1. One or two Functional Stimulation Cuffs (L300 Lower Leg and Thigh), that include surface electrodes.

2. External Pulse Generator (EPG) for the lower leg and EPG for thigh. Both EPG's deliver stimulation to their respective cuffs, and have user interface, including visual, audio, and tactile feedback. Lower EPG can use motion sensor based algorithm to detect heel events.
3. A Control Unit that allows simple wireless remote control of the EPG's while displaying real-time information regarding the system's status.
4. An optional Gait Sensor, which uses a dynamic gait tracking algorithm to detect heel events and wirelessly synchronizes stimulation.
5. A Clinician's Programming System with software, which is used for system programming by a trained clinician during configuration of the system for optimal fitting to the patient.
6. A power supply with two USB outputs and a proprietary cable to charge the EPG.

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

Substantial Equivalence:

Table 1.0 Basic Unit Characteristics

	Current submission L300 Go System	**Predicate L300 Plus System**	**Predicate L300 System**	**Predicate WalkAide System**
1. 510(k) Number and Indication for Use	K162407 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 individuals with muscle weakness related to upper 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 may also improve individual's gait. The L300 Go System may also: • facilitate muscle reeducation, • prevent/retard disuse atrophy, • maintain or increase joint range of motion • increase local blood flow	K103343 The Ness L300 Plus 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 L300 Plus System electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot and flexion or extension, thus it may improve the individual's gait. The L300 Plus System may also: , • facilitate muscle reeducation • prevent/retard disuse atrophy, • maintain or increase joint range of motion • increase local blood flow.	K122784 The Ness L300 Foot Drop System is intended to provide ankle dorsiflexion in individuals (adult and pediatrics) who have foot drop following an upper motor neuron injury or disease. During the swing phase of gait, the Ness L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot . The Ness 300 may improve : • gait, • facilitate muscle reeducation, • prevent/retard disuse atrophy, • maintain or increase joint range of motion • increase local blood flow.	K140886 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 walking, the WalkAide electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the gait in patients with chronic stroke. walking ability. Medical benefits of Functional Electrical Stimulation (FES) may include: • prevent /retardation of disuse atrophy • increased local blood flow, • muscle reeducation, and • maintained or increased joint range of motion
2. Device Name, Model	L300 Go	L300 Plus	L300	WalkAide

3. Manufacturer	Bioness Inc. 25103 Rye Canyon Loop, Valencia, CA 91355	Bioness Neuromodulation, a Bioness Inc. company 8 Hanagar Street, Hod Hasharon, 4501309 Israel	Bioness Neuromodulation, a Bioness Inc. company 8 Hanagar Street, Hod Hasharon, 4501309 Israel	Innovative Neurotronics 4999 Aircenter Cir #103, Reno, NV 89502
4. Power Source(s)	Battery operated	Battery operated	Battery operated	Battery operated
- Method of Line Current Isolation	N/A (Battery operated)	N/A (Battery operated)	N/A (Battery operated)	N/A (Battery operated)
- Patient Leakage current	As required by IEC 60601-1	As required by IEC 60601-1	As required by IEC 60601-1	Information is not available
○ Normal condition	Less than 1.0 µA	Less than 1.3 µA	Less than 1.3 µA	Information is not available
○ Single fault condition	3.0 µA	9.5 µA	9.5 µA	Information is not available
5. Number of output modes	Two modes: Biphasic Symmetric and Biphasic Asymmetric. Applicable to both lower leg and thigh position of the device.	Two modes: Biphasic Symmetric and Biphasic Asymmetric. Applicable to both lower leg (L300 RFS) and thigh (Thigh RFS) position of the device.	Two modes: Biphasic Symmetric and Biphasic Asymmetric. Applicable to lower leg only.	One Mode: Biphasic Asymmetric. Applicable to lower leg only.
6. Number of output channels	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	Lower leg small cuff – 1 channel (L300 RFS) Lower leg regular cuff – 1 channel Thigh cuff – 1 channel (Thigh RFS)	Lower leg small cuff – 1 channel (L300 RFS) Lower leg regular cuff – 1 channel N/A	Lower leg cuff – 1 channel Lower leg regular cuff – 1 channel N/A
- Synchronous or Alternating?	Alternating (at one time only one channel is activated)	N/A	N/A	N/A
- 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 lower leg and thigh cuff stimulators: Thigh and Lower cuffs are stimulated by different battery operated RFS units without galvanic connection between them.	N/A	N/A

	Isolation between channels within the same stimulator: channels in the same EPG are switched using high voltage FET switches.	N/A	N/A	N/A
7. Regulated current or regulated voltage?	Current	Current	Current	Voltage
8. Software / Firmware / Microprocessor Control?	Yes	Yes	Yes	Yes
9. Automatic Overload Trip?	Yes	Yes	Yes	No
10. Automatic No-Load Trip	Yes	Yes	Yes	No
11. Automatic Shut off?	Yes	Yes	Yes	No
12. Patient Override Control?	Yes	Yes	Yes	Yes
13. Indication Display	Yes	Yes	Yes	Yes
- On/Off Status	Yes	Yes	Yes	Yes
- Low battery	Yes	Yes	Yes	Yes
- Voltage / Current Level?	Yes	Yes	Yes	Yes
14. Timer range (minutes)	Gait mode: 1-10 seconds Max stimulation duration (clinician selectable) Training mode: 5-60 minutes	Gait mode: 2-10 seconds Max stimulation duration (clinician selectable) Training mode: 5-60 minutes	Gait mode: 2-10 seconds Max stimulation duration (clinician selectable) Training mode: 5-60 minutes	Gait mode: 0.2-3 seconds Max stimulation duration (clinician selectable) Exercise mode: 1-30 minutes
15. Compliance with Voluntary Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, FCC part 15 subpart C and B1	IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-10, FCC part 15 subpart C and B1	IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-10, FCC part 15 subpart C and B1	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10
16. Compliance with 21 CFR 898?	Yes	Yes	Yes	Yes
17. Weight	Control Unit: 60 g EPG: 60 g Lower leg FSC:150	Control Unit: 45 g L300 RFS: 50 g Thigh RFS: 50 g L300 FSC: 150 g	Control Unit: 45 g L300 RFS: 50 g L300 FSC: 150 g	Control Module: 88 g

	g Thigh cuff: 300 g Foot Sensor: 25 g	Thigh FSC: 330 g Gait Sensor: 30 g	 Gait Sensor: 30 g	
18. Dimensions [W x H x D]	Control Unit: 75x40x17 mm EPG: 82x47x15 mm Lower leg FSC: 160x100x125 mm Thigh FSC: Length: 200 mm Circumference (min): Proximal panel: 270 mm Distal panel (regular): 310 mm Foot Sensor (dimensions of the Transmitter): 65x50x10: mm	Control Unit: 73x46x18 mm L300 RFS: 74x43x15 mm Thigh RFS: 74x43x15 mm L300 FSC: 160x100x125 mm Thigh FSC: Length: 170-260 mm Circumference (min): Proximal panel: 240 mm Distal panel (regular): 300 mm Gait Sensor (dimensions of the Transmitter): 80x50x10 mm	Control Unit: 73x46x18 mm L300 RFS: 74x43x15 mm L300 FSC: 160x100x125 mm Gait Sensor (dimensions of the Transmitter): 80x50x10 mm	Control Module: 82x61x21 mm
19. Housing Materials and Construction	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)	Control Unit: PC-ABS L300 RFS: polyamide 12 with 30% glass fibers reinforcement + Transparent ABS Thigh RFS: PC-ABS L300 FSC: Biocompatible fabric over plastic (POM Hi) skeleton. Thigh FSC: TPU Foot Sensor: ABS	Control Unit: PC-ABS L300 RFS: polyamide 12 with 30% glass fibers reinforcement + Transparent ABS L300 FSC: Biocompatible fabric over plastic (POM Hi) skeleton. Foot Sensor: ABS	Control Module: ABS

Table 2a. Output Specifications (Mode 1 – biphasic symmetrical output)

MODE 1 – BIPHASIC SYMMETRICAL	**Current submission L300 Go System**	**Predicate L300 Plus System**	**Predicate L300 System**	**Predicate WalkAide System**
1. Waveform	Biphasic Symmetrical	Biphasic Symmetrical	Biphasic Symmetrical	Biphasic Asymmetrical only
2. Shape	Rectangular	Rectangular	Rectangular	N/A
3. Maximum Output Voltage (+/- 10%)	Lower leg: 50V @ 500 Ω Thigh: 50V @ 500 Ω	Lower leg: 40V @ 500 Ω Thigh: 50V @ 500 Ω	Lower leg: 40V @ 500 Ω Thigh: N/A	N/A
	Lower leg: 130V @ 2 kΩ Thigh: 130V @ 2 kΩ	Lower leg: 120V @ 2 kΩ Thigh: 120V @ 2 kΩ	Lower leg: 120V @ 2 kΩ Thigh: N/A	N/A
	Lower leg: 130V @ 10 kΩ Thigh: 130V @ 10 kΩ	Lower leg: 120V @ 10 kΩ Thigh: 120V @ 10 kΩ	Lower leg: 120V @ 10 kΩ Thigh: N/A	N/A
4. Maximum Output Current (+/- 10%)	Lower leg: 100mA @ 500 Ω Thigh: 100mA @ 500 Ω	Lower leg: 80mA @ 500 Ω Thigh: 100mA @ 500 Ω	Lower leg: 80mA @ 500Ω Thigh: N/A	N/A
	Lower leg: 65mA @ 2 kΩ Thigh: 65mA @ 2 kΩ	Lower leg: 60mA @ 2 kΩ Thigh: 60mA @ 2 kΩ	Lower leg: 60mA @ 2 kΩ Thigh: N/A	N/A
	Lower leg: 13mA @ 10 kΩ Thigh: 13mA @ 10 kΩ	Lower leg: 12mA @ 10 kΩ Thigh: 12mA @ 10 kΩ	Lower leg: 12mA @ 10 kΩ Thigh: N/A	N/A
5. Pulse width	100, 150, 200, 250, 300 µs (each: positive and phase) Interphase period µs: 50, 100, 200 Total pulse duration: 250, 350, 450, 550, 650 µs (for interphase interval of 50 µs)	100, 200, 300 µs (each: positive and phase) Interphase period µs: 50 Total pulse duration: 250, 450, 650 µs	100, 200, 300 µs (each: positive and phase) Interphase period µs: 50 Total pulse duration: 250, 450, 650 µs	N/A
6. Frequency	10, 15, 20, 25, 30, 35, 40, 45 Hz	20, 25, 30, 35, 40, 45 Hz	20, 25, 30, 35, 40, 45 Hz	N/A
7. For interferential modes only: Beat Frequency.	N/A	N/A	N/A	N/A
8. For multiphasic waveforms only:	Yes	Yes	Yes	N/A
- Symmetrical phases?	Yes	Yes	Yes	N/A

- Phase Duration	Positive phase: 100, 150, 200, 250, 300 µs Negative phase: 100, 150, 200, 250, 300 µs	Positive phase: 100, 200, 300 µs Negative phase: 100, 200, 300 µs	Positive phase: 100, 200, 300 µs Negative phase: 100, 200, 300 µs	N/A
9. Net Charge (µC per pulse) @ 500 Ω	0 µC, using inverted balanced phases	0 µC, using inverted balanced phases	0 µC, using inverted balanced phases	N/A
10. Maximum Phase Charge (µC) @ 500 Ω	Lower leg: 300 µs * 100 mA = 30 µC Thigh: 300 µs * 100 mA = 30 µC	Lower leg: 300 µs * 80 mA = 24 µC Thigh: 300 µs * 100 mA = 30 µC	Lower leg: 300 µs * 80 mA = 24 µC Thigh: N/A	N/A
11. Maximum Current Density @ 500 Ω	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/cm^2 (rms), for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 1.04 mA/cm^2 (rms), for smallest electrodes area of 15.8 cm^2 Thigh: 0.23 mA/cm^2 (rms), for smallest electrodes area of 72 cm^2	Maximum current levels are: Lower leg: 13.15 mA (rms) Thigh: 16.43 mA (rms) Maximum current density is: Lower leg (small cuff): 1.30 mA/cm^2 (rms), for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 0.83 mA/cm^2 (rms), for smallest electrodes area of 15.8 cm^2 Thigh: 0.23 mA/cm^2 (rms), for smallest electrodes area of 72 cm^2	Maximum current levels are: Lower leg: 13.15 mA (rms) Thigh: N/A Maximum current density is: Lower leg (small cuff): 1.30 mA/cm^2 (rms), for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 0.83 mA/cm^2 (rms), for smallest electrodes area of 15.8 cm^2 Thigh: N/A	N/A
12. Maximum Power Density @ 500 Ω	Lower leg (small cuff): 13.4 mW/cm^2, for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 8.5 mW/cm^2, for	Lower leg (small cuff): 8.6 mW/cm^2, for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 5.5 mW/cm^2, for	Lower leg (small cuff): 8.6 mW/cm^2, for smallest electrodes area of 10.1 cm^2 Lower leg	N/A

	smallest electrodes area of 15.8 cm^2 Thigh: 1.9 mW/cm^2, for smallest electrodes area of 72 cm^2	smallest electrodes area of 15.8 cm^2 Thigh: 1.9 mW/cm^2, for smallest electrodes area of 72 cm^2	(regular cuff): 5.5 mW/cm^2, for smallest electrodes area of 15.8 cm^2 Thigh: N/A	
13. Burst Mode	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. If Foot Sensor is on the contralateral leg, pulse bursts are triggered by 'heel contact' and are terminated by 'heel off'. Thigh: Pulse bursts can be triggered either by 'heel off' or 'heel contact' events (or both). Burst terminated by timer or the complementary event.	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. Thigh: Pulse bursts can be triggered either by 'heel off' or 'heel contact' events (or both). Burst terminated by timer or the complementary event.	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. Thigh: N/A	N/A
a. Pulses per burst	Pulses per burst = Burst duration * Pulse frequency	Pulses per burst = Burst duration * Pulse frequency	Pulses per burst = Burst duration * Pulse frequency	N/A
b. Bursts per second	Lower leg: Bursts per second = Strides per second Thigh: Bursts per second = 2 * Strides per second	Lower leg: Bursts per second = Strides per second Thigh: Bursts per second = 2 * Strides per second	Lower leg: Bursts per second = Strides per second Thigh: N/A	N/A
c. Burst duration	Lower leg: Burst duration = Swing duration Thigh: Burst duration ≈ 40%*Swing duration (typically 60% of stride duration) + 60%*Stance duration (typically 40% of stride duration) Total = 0.4*0.6+0.6*0.4 ≈ 48% of stride duration	Lower leg: Burst duration = Swing duration Thigh: Burst duration ≈ 40%*Swing duration (typically 60% of stride duration) + 60%*Stance duration (typically 40% of stride duration) Total = 0.4*0.6+0.6*0.4 ≈ 48% of stride duration	Lower leg: Burst duration = Swing duration Thigh: N/A	N/A

d. Duty cycle [Line (b) x Line (c)]	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: Duty cycle: ≈ 48% (0.4*0.6+0.6*0.4)	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: Duty cycle: ≈ 48% (0.4*0.6+0.6*0.4)	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: N/A	N/A
14. ON Time	Training mode: 4-20 sec Gait mode: 1-10 sec (the max stimulation duration after triggering event is detected)	Training mode: 4-20 sec Gait mode: 2-10 sec (the max stimulation duration after triggering event is detected)	Training mode: 4-20 sec Gait mode: 2-10 sec (the max stimulation duration after triggering event is detected)	N/A
15. OFF Time	Training mode: 4-20 sec Gait mode: not limited	Training mode: 4-60 sec Gait mode: not limited	Training mode: 4-60 sec Gait mode: not limited	N/A

Table 2b. Output Specifications (Mode 2 – biphasic asymmetrical output)

MODE 1 – BIPHASIC ASYMMETRICAL	**Current submission L300 Go System**	**Predicate L300 Plus System**	**Predicate L300 System**	**Predicate WalkAide System**
1. Waveform	Biphasic Asymmetrical	Biphasic Asymmetrical	Biphasic Asymmetrical	Biphasic Asymmetrical
2. Shape	Rectangular	Rectangular	Rectangular	Rectangular
3. Maximum Output Voltage (+/- 10%)	Lower leg: 50V @ 500 Ω Thigh: 50V @ 500 Ω	Lower leg: 40V @ 500 Ω Thigh: 50V @ 500 Ω	Lower leg: 40V @ 500 Ω Thigh: N/A	Lower leg: 101V @ 500 Ω Thigh: N/A
	Lower leg: 130V @ 2 kΩ Thigh: 130V @ 2 kΩ	Lower leg: 120V @ 2 kΩ Thigh: 120V @ 2 kΩ	Lower leg: 120V @ 2 kΩ Thigh: N/A	Lower leg: 134V @ 2 kΩ Thigh: N/A
	Lower leg: 130V @ 10 kΩ Thigh: 130V @ 10 kΩ	Lower leg: 120V @ 10 kΩ Thigh: 120V @ 10 kΩ	Lower leg: 120V @ 10 kΩ Thigh: N/A	Lower leg: 146V @ 10 kΩ Thigh: N/A
4. Maximum Output Current (+/- 10%)	Lower leg: 100mA @ 500 Ω Thigh: 100mA @ 500 Ω	Lower leg: 80mA @ 500 Ω Thigh: 100mA @ 500 Ω	Lower leg: 80mA @ 500 Ω Thigh: N/A	Lower leg: 202 mA @ 500 Ω Thigh: N/A
	Lower leg: 65mA @ 2 kΩ Thigh: 65mA @ 2 kΩ	Lower leg: 60mA @ 2 kΩ Thigh: 60mA @ 2 kΩ	Lower leg: 60mA @ 2 kΩ Thigh: N/A	Lower leg: 67 mA @ 2 kΩ Thigh: N/A
	Lower leg: 13mA	Lower leg: 12mA	Lower leg:	Lower leg: 15

	@ 10 kΩ Thigh: 13mA @ 10 kΩ	@ 10 kΩ Thigh: 12mA @ 10 kΩ	12mA @ 10 kΩ Thigh: N/A	mA @ 10 kΩ Thigh: N/A
5. Pulse width	Positive phase: 100, 150, 200, 250, 300 µs Negative phase: 300, 450, 600, 750, 900 µs Interphase period: 50, 100, 200 µs Total pulse duration: 600, 800, 1000, 1200, 1400 µs (for interphase interval of 200 µs)	Positive phase: 100, 200, 300 µs Negative phase: 400, 800, 1200 µs Interphase period: 0 µs Total pulse duration: 500, 1000, 1500 µs	Positive phase: 100, 200, 300 µs Negative phase: 400, 800, 1200 µs Interphase period: 0 µs Total pulse duration: 500, 1000, 1500 µs	15, 50, 100, 150, 200, 250, 300 µs
6. Frequency	10, 15, 20, 25, 30, 35, 40, 45 Hz	20, 25, 30, 35, 40, 45 Hz	20, 25, 30, 35, 40, 45 Hz	16.7, 20.0, 25.0, 33.3 Hz
7. For interferential modes only: Beat Frequency.	N/A	N/A	N/A	N/A
8. For multiphasic waveforms only:	Yes	Yes	Yes	Yes
- Symmetrical phases? -	No	No	No	No
- Phase Duration	Positive phase: 100, 150, 200, 250, 300 µs Negative phase: 300, 450, 600, 750, 900 µs	Positive phase: 100, 200, 300 µs Negative phase: 400, 800, 1200 µs	Positive phase: 100, 200, 300 µs Negative phase: 400, 800, 1200 µs	Information is not available
9. Net Charge (µC per pulse) @ 500 Ω	0 µC, using inverted balanced phases	0 µC, using inverted balanced phases	0 µC, using inverted balanced phases	Information is not available
10. Maximum Phase Charge (µC) @ 500 Ω	Lower leg: 300 µs * 100 mA = 30 µC Thigh: 300 µs * 100 mA = 30 µC	Lower leg: 300 µs * 80 mA = 24 µC Thigh: 300 µs * 100 mA = 30 µC	Lower leg: 300 µs * 80 mA = 24 µC Thigh: N/A	Lower leg: 50 µC Thigh: N/A
11. Maximum Current Density @ 500 Ω	Maximum current levels are: Lower leg: 13.42 mA (rms) Thigh: 13.42 mA (rms)	Maximum current levels are: Lower leg: 10.39 mA (rms) Thigh: 13.0 mA (rms)	Maximum current levels are: Lower leg: 10.39 mA (rms) Thigh: N/A	Maximum current levels are: Lower leg: 20.7 mA (rms) Thigh: N/A

	Maximum current density is: Lower leg (small cuff): 1.33 mA/cm^2 (rms), for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 0.85 mA/cm^2 (rms), for smallest electrodes area of 15.8 cm^2 Thigh: 0.19 mA/cm^2 (rms), for smallest electrodes area of 72 cm^2	Maximum current density is: Lower leg (small cuff): 1.03 mA/cm^2 (rms), for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 0.66 mA/cm^2 (rms), for smallest electrodes area of 15.8 cm^2 Thigh: 0.18 mA/cm^2 (rms), for smallest electrodes area of 72 cm^2	Maximum current density is: Lower leg (small cuff): 1.03 mA/cm^2 (rms), for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 0.66 mA/cm^2 (rms), for smallest electrodes area of 15.8 cm^2 Thigh: N/A	Maximum current density is: Lower leg: 2.62 mA/cm^2 (rms), for smallest electrodes area of 7.9 cm^2 (round, 3.175 cm diameter electrodes) Thigh: N/A
12. Maximum Power Density @ 500 Ω	Lower leg (small cuff): 8.9 mW/cm^2, for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 5.7 mW/cm^2, for smallest electrodes area of 15.8 cm^2 Thigh: 1.3 mW/cm^2, for smallest electrodes area of 72 cm^2	Lower leg (small cuff): 5.3 mW/cm^2, for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 3.4 mW/cm^2, for smallest electrodes area of 15.8 cm^2 Thigh: 1.2 mW/cm^2, for smallest electrodes area of 72 cm^2	Lower leg (small cuff): 5.3 mW/cm^2, for smallest electrodes area of 10.1 cm^2 Lower leg (regular cuff): 3.4 mW/cm^2, for smallest electrodes area of 15.8 cm^2 Thigh: N/A	Lower leg (small cuff): 27.6 mW/cm^2, for smallest electrodes area of 7.9 cm^2 Thigh: N/A
13. Burst Mode	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. If Foot Sensor is on the contralateral leg, pulse bursts are triggered by 'heel contact' and are terminated by 'heel off'. Thigh: Pulse bursts can be triggered either by 'heel off' or 'heel contact' events (or	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. Thigh: Pulse bursts can be triggered either by 'heel off' or 'heel contact' events (or both). Burst terminated by	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. Thigh: N/A	Lower leg: Pulse bursts are triggered by 'heel off' and terminated by 'heel contact' events during gait cycle. Thigh: N/A

	both). Burst terminated by timer or the complementary event.	timer or the complementary event.		
a. Pulses per burst	Pulses per burst = Burst duration * Pulse frequency	Pulses per burst = Burst duration * Pulse frequency	Pulses per burst = Burst duration * Pulse frequency	Pulses per burst = Burst duration * Pulse frequency
b. Bursts per second	Lower leg: Bursts per second = Strides per second Thigh: Bursts per second = 2 * Strides per second	Lower leg: Bursts per second = Strides per second Thigh: Bursts per second = 2 * Strides per second	Lower leg: Bursts per second = Strides per second Thigh: N/A	Lower leg: Bursts per second = Strides per second Thigh: N/A
c. Burst duration	Lower leg: Burst duration = Swing duration Thigh: Burst duration ≈ 40%*Swing duration (typically 60% of stride duration) + 60%*Stance duration (typically 40% of stride duration) Total = 0.4*0.6+0.6*0.4 ≈ 48% of stride duration	Lower leg: Burst duration = Swing duration Thigh: Burst duration ≈ 40%*Swing duration (typically 60% of stride duration) + 60%*Stance duration (typically 40% of stride duration) Total = 0.4*0.6+0.6*0.4 ≈ 48% of stride duration	Lower leg: Burst duration = Swing duration Thigh: N/A	Lower leg: Burst duration = Swing duration Thigh: N/A
d. Duty cycle [Line (b) x Line (c)]	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: Duty cycle: ≈ 48% (0.4*0.6+0.6*0.4)	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: Duty cycle: ≈ 48% (0.4*0.6+0.6*0.4)	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: N/A	Lower leg: Duty cycle of 50-70% (swing ratio in a typical subject) Thigh: N/A
14. ON Time	Training mode: 4-20 sec Gait mode: 1-10 sec (the max stimulation duration after triggering event is	Training mode: 4-20 sec Gait mode: 2-10 sec (the max stimulation duration after triggering event is	Training mode: 4-20 sec Gait mode: 2-10 sec (the max stimulation duration after triggering event is	Training mode: 1-5 sec Gait mode: max 5 sec (the max stimulation duration after triggering

	detected)	detected)	detected)	event is detected)
15. OFF Time	Training mode: 4-20 sec Gait mode: not limited	Training mode: 4-60 sec Gait mode: not limited	Training mode: 4-60 sec Gait mode: not limited	Training mode: 1-10 sec Gait mode: not limited

The L300 Go System is substantially equivalent to a combination of both its own prior generation devices, the NESS L300 Plus System, cleared for marketing under K103343, the NESS L300 System, cleared for marketing under K122784, and the Innovative Neurotronics, Inc. WalkAide System, cleared for marketing under K140886. The L300 Go System does not introduce any new issues of safety or efficacy relative to either of these predicate devices.

The primary predicate device is the NESS L300 Plus, which is included in the L300 Go System almost in its entirety.

The L300 Go System incorporates all of the NESS L300 Plus components, including the following updates:

1. Bioness-proprietary wireless communication technology is being replaced with industry-standard Bluetooth (low energy) wireless communication technology.
2. Limited User Interface (*i.e.,* used via Remote Control only) is being replaced with an expanded User Interface (that can be used either via or via Stimulator-based interface).
3. PDA-based Clinician Programmer is being replaced with and a Tablet/PC-based Clinician Programmer.

Thus, the L300 Go System incorporates all of the NESS L300 Plus components including a few other minor technological improvements listed above as compared to the predicate NESS L300 Plus.

One additional change in the L300 Go System is its design that now allows the clinician to use either one *or* two stimulation channels, rather than just the single channel available for use with the latter device (as is also the case with the WalkAide). However, this two-channel option in the L300 Go System simply allows the clinician to more precisely adjust foot eversion/inversion, does not introduce any new concerns of safety or efficacy, and is still operational just as a

single-channel stimulator.

The L300 Go System also incorporates a tilt sensor very similar to that used in the WalkAide where (just as in the predicate device) that stimulation trigger mechanism can be used during gait, instead of a foot sensor as an alternative trigger source. However, both systems can also still employ the foot sensor with users for whom the tilt sensor cannot be used adequately.

Finally, the L300 Go System and both of its predicates can be used not only for improving gait but also for providing exercise functions. However, this feature is limited in the WalkAide device only to the lower leg, while it is available for use with the Bioness products for providing exercise functions in both the lower *and* upper leg.

Overall, then, the L300 Go System shares essentially the same intended use, technology, and stimulation methods and main components with its two predicate devices.

Conclusion:

Bioness believes that the L300 Go System is substantially equivalent to the NESS L300 Plus System (K103343), NESS L300 System (K122784) and the Innovation Neurotronics WalkAide System (K140886) predicate devices, and does not raise any new issues or concerns of safety or effectiveness.