September 12, 2019

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

Re: K191587
Trade/Device Name: L360 Thigh System
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: June 11, 2019
Received: June 14, 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/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,

Vivek Pinto, PhD
Director (Acting)
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)*
K191587

Device Name
L360 Thigh System

Indications for Use *(Describe)*
The L360 Thigh System is intended 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 L360 Thigh System electrically stimulates muscles in the affected leg to provide knee flexion or extension; thus, it also may improve the individual's gait.

The L360 Thigh System may also:
- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow
- Provide early post-surgical quadricep and hamstring strengthening
- Improve post-surgical knee stability secondary to quadricep and hamstring strengthening
- Relax muscle spasms

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

510(k) Summary: L360 Thigh System

Applicant Name: Bioness Inc.

Contact person (s):

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Date prepared: September 12, 2019

Device Trade Name: L360 Thigh 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: Expansion of the Indication for Use

Type of Submission: Traditional 510(k)

Predicate devices:

1. Company: Bioness Inc.
   Device: L300 Go System (K190285)
2. Company: Bio-Medical Research, Ltd.
   Device: Kneehab XP, Type 412/421 (K110350)

Purpose of the traditional 510(k) notice:

The L360 Thigh System is the Thigh Standalone configuration of its predicate device, the L300 Go System, with expanded indication for use. The L360 Thigh System is substantially equivalent to its own superset device, the L300 Go System, and the Bio-Medical Research Ltd. Kneehab XP, Type 412/421(hereinafter referred to as Kneehab XP).

Device description:

The L360 Thigh System is intended 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 L360 Thigh System electrically stimulates muscles in the affected leg to provide knee flexion or extension; thus, it also may improve the individual's gait.

The L360 Thigh System consists of:

1. One or two Thigh Functional Stimulation Cuffs (Thigh Cuff) that include surface electrodes.
2. Central External Pulse Generator (EPG). The EPG delivers stimulation to their respective cuffs, and have user interface, including visual, audio, and tactile feedback. The EPG can use motion sensor based algorithm to detect heel events.
3. An optional 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. An optional Mobile Application (MAPP) enabling the patients to wirelessly control the EPG(s) and retrieve and monitor their daily activity.
7. A power supply with two USB outputs and a proprietary cable to charge the EPG(s).

Indications for use:

The L360 Thigh System is intended 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 L360 Thigh System electrically stimulates muscles in the affected leg to provide knee flexion or extension; thus, it also may improve the individual's gait.

The L360 Thigh System may also:

• Facilitate muscle re-education

• Prevent/retard disuse atrophy

• Maintain or increase joint range of motion

• Increase local blood flow

• Provide early post-surgical quadricep and hamstring strengthening

• Improve post-surgical knee stability secondary to quadricep and hamstring strengthening

• Relax muscle spasms

Substantial Equivalence:

The table on next page summarize the indication for use and technological characteristics of the new device in comparison to those of the predicate devices.

	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Manufacturer	Bioness Inc.	Bioness Inc.	Bio-Medical Research Ltd.
510(k) number	To be assigned_____	K190285	K110350
Product Code	GZI & IPF	GZI & IPF	IPF, GZJ, NYN
Prescription Use	Yes	Yes	Yes
Indication for Use Statement	The L360 Thigh System is intended 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 L360 Thigh System electrically stimulates muscles in the affected leg to provide knee flexion or extension; thus, it also may improve the individual's gait. The L360 Thigh System may also: • Facilitate muscle re-education • Prevent/retard disuse atrophy • Maintain or increase joint range of motion • Increase local blood flow • Provide early post-surgical quadriceps and hamstring strengthening • Improve post-surgical knee stability secondary to quadriceps and hamstring strengthening • Relax muscle spasms	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	In NMES mode (Programs 1-6) the Kneehab XP is intended to: • Maintain or increase the range of motion • Prevention or retardation of disuse atrophy • Re-educate muscles • Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening • Relax muscle spasms • Increase blood circulation In TENS Mode (Programs 7-9) the Kneehab XP is intended to: • Provide symptomatic relief and management of chronic, intractable pain • Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain • Provide symptomatic relief and management of intractable pain and relief of pain associated with arthritis Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee
Energy source	3.7V, 1000mAh Lithium ion rechargeable prismatic battery	3.7V, 1000mAh Lithium ion rechargeable prismatic battery	3.6V NiMH rechargeable battery pack

Table continues next page

	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Housing Material and Construction	Control Unit: Bay State Polymer PA-2000RX EPG: Bay State Polymer PA-2000RX Thigh FSC: TPU Foot Sensor: ABS (Sensor housing), Bay state Polymer PA-2000RX (Electronics housing)	Control Unit: Bay State Polymer PA-2000RX EPG: Bay State Polymer PA-2000RX Thigh FSC: TPU Foot Sensor: ABS (Sensor housing), Bay state Polymer PA-2000RX (Electronics housing)	Control Unit: ABS-PA-757) Garment: Contains EEPROM (A Outer fabric: 100% Nylon Inner fabric: 70% Polychloroprene & 30% Polyurethane Binding: 82% Nylon & 18% Elastane Fastening: 100 Nylon
Electrode	Two non-woven cloth electrodes, oval (Proximal 130x75mm, 91.1cm^2 and Distal 120x63mm, 72cm^2) Constructed from non-conductive plastic back, stainless steel mesh, and cloth facing towards the leg.	Two non-woven cloth electrodes, oval (Proximal 130x75mm, 91.1cm2 and Distal 120x63mm, 72cm2) Constructed from non-conductive plastic back, stainless steel mesh, and cloth facing towards the leg.	Four gel pad electrodes Electrode A: 194 cm^2 Electrode B: 74 cm^2 Electrode C: 83 cm^2 Electrode D: 66 cm^2
Lead wires	Wires embedded in the cuff	Wires embedded in the cuff	Over-molded SATA connector splitting to 5 leads / studs embedded in the garment
Stimulation Site	Quadriceps or Hamstring	Quadriceps or Hamstring	Quadriceps
Standards Met	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-10 IEC 62304 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10 21 CFR 801 21 CFR 898	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-10 IEC 62304 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10 21 CFR 801 21 CFR 898	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10 21 CFR 898 21 CFR 801
Method of line isolation	N/A (battery operated)	N/A (battery operated)	No line connection (battery operated)
Patient Leakage current	Normal condition: Less than 1.0µA (as required by IEC 60601- 1) Single fault condition: 3.0µA (as required by IEC 60601-1)	Normal condition: Less than 1.0µA (as required by IEC 60601-1) Single fault condition: 3.0µA (as required by IEC 60601-1)	Information is not available

	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Stimulation Modes	- Gait - Training - Cycle Training - Clinician	- Gait - Training - Cycle Training - Clinician	NMES (Programs 1-6) TENS (Programs 7-10)
Waveform/ shape	Pulsed, Biphasic, Rectangular with interphase interval	Pulsed, Biphasic, Rectangular with interphase interval	Pulsed, Biphasic, Rectangular with interphase interval
Number of output channels	1 channel (EPG has 2 channels, but only 1 channel is connected to the thigh cuff electrodes)	Thigh cuff: 1 channel (EPG has 2 channels, but only 1 channel is connected to the thigh cuff electrodes)	2
Synchronous or Alternating?	N/A, only one output channel	N/A, only one output channel for thigh cuff	Synchronous (multiplexed)
Method of Channel Isolation	N/A, only one output channel	N/A, only one output channel for thigh cuff	Transistor
Regulated current or voltage	Current	Current	Current
Software / Firmware / Microprocessor Control?	Yes	Yes	Yes
Automatic overload trip?	Yes	Yes	Yes, current limited, indefinite short circuit allowed
Automatic No-load trip?	Yes	Yes	Yes
Automatic shut off?	Yes	Yes	Yes
Patient override control?	Yes	Yes	Yes, pause button
Indicator Display:			
On/Off Status?	Yes	Yes	Yes
Lower Battery?	Yes	Yes	Yes
Voltage/ Current Level?	Yes	Yes	Yes

Table continues next page

	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Timer range	Gait mode: N/A, stimulation timing is determined by heel on / heel off events Cycle Training Mode: N/A, stimulation timing is determined by position of the pedals Training mode: 5-60 minutes	Gait mode: N/A, stimulation timing is determined by heel on / heel off events Cycle Training Mode: N/A, stimulation timing is determined by position of the pedals Training mode: 5-60 minutes	20 min > - open
Compliance with 21 CFR 898?	Yes	Yes	Yes
Weight	EPG: 60g Thigh cuff: 300g	EPG: 60g Thigh cuff: 300g	Control Unit: 116g (inc. batteries)
Dimensions (W x H x D)	EPG: 82x47x15mm Thigh cuff: - Length: 200mm - Circumference (min) • Proximal panel: 270mm Distal panel: 310mm	EPG: 82x47x15mm Thigh cuff: - Length: 200mm - Circumference (min) • Proximal panel: 270mm • Distal panel: 310mm	Control Unit: 60x32x115mm
Frequency / Phase duration	Frequency: 10, 15, 20, 25, 30, 35, 40, 45 Hz Symmetric and Asymmetric positive: 100, 150, 200, 250, 300 µs Asymmetric Negative: 300, 450, 600, 750, 900 µs	Frequency: 10, 15, 20, 25, 30, 35, 40, 45 Hz Symmetric and Asymmetric positive: 100, 150, 200, 250, 300 µs Asymmetric Negative: 300, 450, 600, 750, 900 µs	300µsNMES Programs: P1: 50 Hz, 300 - 400 µs P2: 50 Hz, 300 - 400 µs P3: 50 Hz, 300 - 400 µs P4: 50 Hz, 300 - 400 µs P5: 35 Hz, 300 - 400 µs P6: 70 Hz, 300 - 400 µs
Baseline to peak current (+/-10%)	100mA @ 500 Ohm 65mA @ 2k Ohm 13mA @ 10k Ohm	100mA @ 500 Ohm 65mA @ 2k Ohm 13mA @ 10k Ohm	80mA @ 500 Ohm 28mA @ 2k Ohm 3.9mA @ 10k Ohm
Baseline to peak output voltage (+/-10%)	50V @ 500 Ohm 130V @ 2k Ohm 130V @ 10k Ohm	50V @ 500 Ohm 130V @ 2k Ohm 130V @ 10k Ohm	40.0V @ 500 Ohm 55.6V @ 2k Ohm 39.3V @ 10k Ohm
Maximum RMS output voltage (+/-10%) Vrms	8.2V @ 500 Ohm 21.3V @ 2 kOhm 21.3 @ 10 kOhm	8.2V @ 500 Ohm 21.3V @ 2 kOhm 21.3 @ 10 kOhm	9.3V @ 500 Ohm 17.1V @ 2kOhm 14.1V @ 10kOhm
Maximum RMS output current (+/-10%) Irms	Symmetric: 16.4mA @ 500 Ohm 10.7mA @ 2 kOhm 2.1mA @ 10 kOhm	Symmetric: 16.4mA @ 500 Ohm 10.7mA @ 2 kOhm 2.1mA @ 10 kOhm	18.6 mA @ 500 Ohm 8.6mA @ 2k Ohm 1.42mA @ 10k Ohm

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	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Pulse width	Positive phase: 100, 150, 200, 250,300µs (positive phase) Interphase interval: 20, 50, 200 µs Total pulse duration for symmetric waveform (for 50 µs interphase interval): 250, 350, 450, 550, 650 µs Total pulse duration for asymmetric waveform (for 50 µs interphase interval): 450, 650, 850, 1050, 1250 µs	Positive phase: 100, 150, 200, 250,300µs (positive phase) Interphase interval: 20, 50, 200 µs Total pulse duration for symmetric waveform (for 50 µs interphase interval): 250, 350, 450, 550, 650 µs Total pulse duration for asymmetric waveform (for 50 µs interphase interval): 450, 650, 850, 1050, 1250 µs	640 µs – sum of both phases 300 µs + 40 µs interphase interval (There is a discrepancy between the 510K summary of the device and the device's IFU).
Net charge (µC per pulse)	0 µC @ 500 Ohm	0 µC @ 500 Ohm	0 µC @ 500 Ohm
Maximum phase charge @ 500 Ohm (+/-20%)	30 µC @ 500 Ohm (300 µs * 100mA)	30 µC @ 500 Ohm (300 µs * 100mA)	24 µC @ 500 Ohm
Maximum current density @ 500 Ohm (mA/cm^2)	0.228 mA/cm^2 (calculated as 16.4 $mA/72cm^2$)	Thigh: 0.228 mA/cm^2 (calculated as 16.4 $mA/72cm^2$)	0.224 mA/cm^2 (calculated as 18.6 $mA/83cm^2$)
Maximum power density @ 500 Ohm using smallest electrode conductive surface area	1.87 mW/cm^2 (500 Ohm, electrode area of $74cm^2$)	1.87 mW/cm^2 (500 Ohm, electrode area of $74cm^2$)	2.1mW/cm^2 @ 500 Ohm

Table continues next page

	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Burst mode	Yes Bursts can be triggered by three different sources: Gait mode: Bursts triggered either by 'heel off' or 'heel contact' events (or both). Cycle Training Mode: Bursts triggered by position of the pedals during pedaling cycle. Training mode: Bursts triggered by on/off settings of the timer.	Yes Bursts can be triggered by three different sources: Gait mode: Bursts triggered either by 'heel off' or 'heel contact' events (or both). Cycle Training Mode: Bursts triggered by position of the pedals during pedaling cycle. Training mode: Bursts triggered by on/off settings of the timer.	Yes Bursts are triggered by on/off settings of the timer, per selected NMES program.
Pulse per burst	Pulses per burst = Burst duration*Frequency	Pulses per burst = Burst duration*Frequency	Pulses per burst = Burst duration*Frequency
Bursts per second	Gait mode: Bursts per second = 2*Strides per second Cycle Training mode: Burst per second = revolutions per second Training mode: Average number of bursts per second = 1 / (time on + time off)	Gait mode: Bursts per second = 2*Strides per second Cycle Training mode: Bursts per second = revolutions per second Training mode: Average number of bursts per second = 1 / (time on + time off)	Average number of bursts per second = 1 / (time on + time off)

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	L360 Thigh System (This submission)	L300 Go System (K190285)	Kneehab XP (K110350)
Duty Cycle (Bursts per second * burst duration)	Gait mode: For example, for pace of one stride per second, Duty Cycle = 0.48 sec * 1 (stride/sec) * 100% = 48% Cycle Training mode: For example, for one revolution per second, Duty cycle = 0.3 sec * 1rps * 100% = 30% Training mode: On time: 4 – 20 sec Off time: 4 – 20 sec Min Duty Cycle = 4 sec * (1/40)(1/sec) * 100% = 10% Max Duty Cycle = 20 sec * (1/24)(1/sec) * 100% = 83%	Gait mode: For example, for pace of one stride per second, Duty Cycle= 0.48 sec * 1 (stride/sec)* 100% = 48% Cycle Training mode: For example, for one revolution per second, Duty cycle = 0.3 sec * 1rps * 100% = 30% Training mode: On time: 4 – 20 sec Off time: 4 – 20 sec Min Duty Cycle = 4 sec * (1/40)(1/sec) * 100% = 10% Max Duty Cycle = 20 sec * (1/24)(1/sec) * 100% = 83%	NMES mode: P1 Duty Cycle = 5 sec * (1/15)(1/sec) * 100% = 33% P2 Duty Cycle = 10 sec * (1/20)(1/sec) * 100% = 50% P3 Duty Cycle = 10 sec * (1/30)(1/sec) * 100% = 33% P4 Duty Cycle = 10 sec * (1/40)(1/sec) * 100% = 25% P5 Duty Cycle = 5 sec * (1/10)(1/sec) * 100% = 33% P6 Duty Cycle = 10 sec * (1/60)(1/sec) * 100% = 17%
Pulse frequency	10, 15, 20, 25, 30, 35, 40, 45 Hz	10, 15, 20, 25, 30, 35, 40, 45 Hz	NMES mode: 35, 50, 70Hz
Ramp up time	0-2 sec (0.5 sec step)	0-2 sec (0.5 sec step)	NMES mode: 0.5 sec
Ramp down time	0-2 sec (0.5 sec step)	0-2 sec (0.5 sec step)	NMES mode: 0.5 sec
On time (contraction time)	4 – 20 sec (1 sec step)	4 – 20 sec (1 sec step)	NMES mode: 5 sec or 10 sec
Off time (relaxation time)	4 – 20 sec (1 sec step)	4 – 20 sec (1 sec step)	NMES mode: 5, 10, 20, 30, or 50 sec

End of table

The L360 Thigh System, subject of this submission is exactly the same device in all aspect to the Thigh Standalone configuration of its predicate device, the L300 Go System, cleared for marketing under K190285. The only difference between the devices is the expansion of the indication to provide relaxation of muscle spasms and post-surgical muscle strengthening and knee stability. The proposed indication for use is supported by its substantial equivalence to that of the Predicate Device #1, the L300 Go System (K190285) and Predicate Device #2, the Kneehab XP (K110350) with regards to its use as a neuromuscular electronic stimulator (NMES),

and additionally supported by scientific literature, the principle of the NMES, and the standard indication for use for Powered Muscle Stimulators classified under 21 CFR 890.5850 (product code: IPF) per FDA Guidance Document for Powered Muscle Stimulator 510(k)s issued on June 9, 1999.

Performance Tests:

Since the L360 Thigh System is a subset and consists of the same components as the Thigh Standalone configuration of the predicate L300 Go System, there are no differences in the technological characteristics between the two devices. Therefore, the performance tests conducted on L300 Go System can also be applied to the L360 Thigh System.

The predicate L300 Go System was qualified through the following electrical, mechanical, and functional testing:

- Lifetime test
- Reliability, mechanical durability
- Environmental conditions testing
- Functional Verification and Validation Tests
- Software Verification and Validation Tests
- Electrical Safety and Electromagnetic Compatibility (EMC)

The conclusions drawn from the performance tests demonstrate that the device is performing as intended, and is substantially equivalent to the predicate devices.

Biocompatibility:

The L360 Thigh System uses the exact same material and has the same type of skin contact as its predicate device, the L300 Go System, so new biocompatibility testing was not run. The predicate device underwent the following biocompatibility test evaluation in accordance with the FDA Good Laboratory Practice and requirements specified under ISO 10993.

- Cytotoxicity
- Sensitization
- Irritation

Conclusion:

Bioness concludes that the L360 Thigh System is substantially equivalent to the company's own L300 Go System (K190285) and the Bio-Medical Research, Ltd.'s, Kneehab XP (K110350) predicate devices, and does not raise any new issues or concerns of safety or effectiveness.