APR 1 2013

510(k) Summary
for the
Innovative Neurotronics, Inc.
WalkAide System
K123972

1. SPONSOR

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2. DEVICE NAME

Proprietary Name: WalkAide
Common/Usual Name: External Neuromuscular Functional Stimulator
Classification Names: External Neuromuscular Functional Stimulator
Classification Number: 21 CFR 882.5810
Product Code: GZI

3. PREDICATE DEVICES

Proprietary Name	510(k)	Product Code	Manufacturer
WalkAide System	K052329	GZI	Innovative Neurotronics, Inc.
NESS L300	K103343	GZI, IPF	Bioness Inc.
ODFS PACE	K102115	GZI	Odstock Medical LTD

4. INTENDED USE

The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (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 gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

5. DEVICE DESCRIPTION

The WalkAide is an external functional electrical stimulator. It is a small device that attaches to the leg just below the knee, near the head of the fibula. During a gait cycle, the WalkAide stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that cause dorsiflexion of the ankle. The WalkAide System consists of the WalkAide Patient Kit and the WalkAide Clinician Kit . The WalkAide Patient Kit comprises of all the components and accessories that the patient will take home and use. The Clinician System comprises the accessories that a clinician (i.e., orthotic specialist, physiotherapist, occupational therapist, etc.) will use to set up a patient's WalkAide.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

WalkAide, Odstock and the Bioness L300 are designed to meet the applicable requirements of IEC 60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators." Not all of this standard is applicable since the standard applies to line powered devices and the WalkAide is powered by one AA batteries. V012 " WalkAide Performance Test Protocol" tests to the applicable requirements of IEC 60601-2-10. When this protocol is run it validates that the WalkAide meets the applicable design requirements of IEC 60601-2-10.

There are basically three changes in Output Specification between the parent WalkAide (K052329) device and the proposed WalkAide (K123972) device: 1) output voltage, 2) output pulse width, and 3) addition of Ramp Modulation (Ramp Up and Ramp Down).

The Output Specifications of the proposed device and the parent device are substantially equivalent. The changes to the output voltage and output pulse width are equivalent to the Bioness and Odstock competitive devices and also still meet the

applicable clauses of IEC 60601-2-10 "Particular Requirements for the Safety of Nerve and Muscle Stimulators". V012 " WalkAide Performance Test Protocol" tests to the applicable requirements of IEC 60601-2-10. The addition of Ramp Up and Ramp Down is equivalent to the ramping of the Bioness and Odstock devices.

For similarities and differences please review the following predicate comparison table:

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K052329	BIONESS L300 PLUS K103343	ODSTOCK PACE K102115	INNOVATIVE NEUROTRONICS, INC. WALKAIDE PROPOSED K123972	COMPARISON
Intended Use	**SUMMARY STATEMENT** The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (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 gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.	**SUMMARY STATEMENT** 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 knee flexion or extension, thus it may improve the individual's gait. The **L300** Plus System may also: * Facilitate Muscle re-education * Prevent/retard disuse atrophy * Maintain or increase joint range of motion * Increase local blood flow	**SUMMARY STATEMENT** The **ODES®** Pace is intended to provide ankle dorsiflexion in individuals who have a dropped foot as a consequence of upper motor neuron injury. **By** detecting the swing phase of gait through a foot switch signal, appropriate electrical stimulation of the leg and ankle muscles may improve gait **by** flexing the foot of persons who have lost or impaired function. There may be additional benefits from **FES** such as muscle re-education, prevention/retardation of disuse atrophy, increased or maintained range of joint motion and increase in local blood flow.	**SUMMARY STATEMENT** The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (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 gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.	Identical Equivalent
Power Source	1.5 V AA Battery (not rechargeable)	CU - Rechargeable AAA Stim – Rechargeable LiIon Gait Sensor – CR2430 coin cell	PP3, 9V Battery	1.5 V AA Battery (not rechargeable)	Identical
Microprocessor Controlled	Yes	Yes	Yes	Yes	Identical
Indicators Unit functioning Low Battery	 Yes Yes	 Yes Yes	 Yes Yes	 Yes Yes	Identical
Patient Device Set-up and Training	Done by a clinician using a Notebook/Tablet PC	All the set-up is done through a PDA	All the set-up is done through the unit	Done by a clinician using a Notebook/Tablet PC	Identical

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K052329	BIONESS L300 PLUS K103343	ODSTOCK PACE K102115	INNOVATIVE NEUROTRONICS, INC. WALKAIDE PROPOSED K123972	COMPARISON
Number of Output Modes	1	2	2	1	Identical
Channels	1	1	1	1	Identical
Output Stage Type Range/Accuracy Load	Constant Voltage (Adjustable) 0 – 78 V (±5%) 1000 Ohm load	Constant Current 0 – 80 mA in 1mA steps <120V Max Load 5000 ohm (subject to Max Voltage Limitation)	Constant Current 10 -- 100 mA ±10% into a 1000 ohm load Approx 4% steps 10 to 110 V (Calculated)	Constant Voltage (Adjustable) 0 – 110V (±10%) 1000 Ohm load	Equivalent
Max Output Current **(IEC 60601-2-10 Specification of 50mA rms Max)**	115 mA peak (±5%) @ 500 Ohm load (max specification limit)	80 mA pk @ 500 Ohm load (measured)	176 mA pk @ 500 Ohm load (measured)	<206.8 mA peak @ 500 Ohm load (max specification limit)	Equivalent
	11.0 mA rms max @ 500 ohm (Computed based on 115 mA (+5%), square pulse)	13.14 mA rms max @ 500 ohm (Computed based on 80 mA square pulse)	25.8 mA rms max @ 500 ohm (Computed based on 176 mA square pulse)	20.7 mA rms max @ 500 ohm (Computed based on 206.8 mA square pulse)	
	8.8 mA rms max @ 500 ohm (measured)	**13.1 mA rms max @ 500 ohm (measured)**	**20.6 mA rms max @ 500 ohm (measured)**	**14.2 mA rms max @ 500 ohm (measured)** **(IEC 60601-2-10 Specification of 50mA rms Max)**	
	78 mA peak (±5%), 1000 Ohm load (max specification limit)	80.7 mA pk @ 1000 Ohm load (measured)	110 mA pk @ 1000 Ohm load (measured)	<121 mA peak @ 1000 Ohm load (max specification limit)	
Max Output Voltage **(IEC 60601-2-10 Specification limit of 500 V Peak)**	78 V 1000 Ohm load	80.7 Vpk @ 1K assym (meas) 161.4 Vp-p @ 1K sym (meas)	108 Vpk @ 1K assym (meas) 216 Vp-p @ 1K sym (meas)	121 V max 1000 Ohm load **(IEC 60601-2-10 Specification limit of 500 V Peak)**	Equivalent
	<150 V 1M Ohm load	120 pk @ 1M assym (meas) 240 Vp-p @ 1M sym (meas)	150V pk @ 1M assym (meas) 350 Vp-p @ 1M sym (meas)	Spec limit <150 V 1M Ohm load 123V pk @ 1M (meas)	Identical

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K052329	BIONESS L300 PLUS K103343	ODSTOCK PACE K102115	INNOVATIVE NEUROTRONICS, INC. WALKAIDE PROPOSED K123972	COMPARISON
Ramp Modulations (for gait ON Ramp Ramp Up Time OFF Ramp Ramp Down Time	No No	Yes 0 to 2 sec in 0.1 sec steps Yes 0 to 2 sec in 0.1 sec steps	Yes 0 to 2 sec in 0.05 sec steps Yes 0 to 2 sec in 0.05 sec steps	Yes 0 to 0.5 sec in 0.1 sec steps Yes 0 to 0.5 sec in 0.1 sec steps	Equivalent
Waveform Monophasic or Biphasic Symmetrical or Asymmetrical Shape	Biphasic Asymmetrical	Balanced Biphasic Symmetrical or Asymmetrical	Biphasic passive charge balanced Symmetrical or Asymmetrical	Biphasic Asymmetrical	Identical
Pulse Duration	50-250 microseconds ± 5% (Adjustable) Pulse duration adjustable in following discrete steps: 50, 100, 150, 200, and 250 µs	100 – 300 microseconds in 100 microsecond steps	0 – 360 microseconds ±10% in 3.6 µs steps	25-300 microseconds. Accuracy ±5% or ±7 microseconds, whichever is greater. Pulse duration adjustable in following discrete steps: 25, 50, 100, 150, 200, 250, and 300 µs	Equivalent
Frequency Range (Pulses per second)	16.7, 20.0, 25.0, and 33.3 pulses per second (Hz)	20 to 45 pps in 5 pps steps	20 to 60 pps ±10% in 5 pps steps	16.7, 20.0, 25.0, and 33.3 pulses per second (Hz)	Identical
Time Between Rising Edge of Pulses	Time adjustable in following discrete steps: 30, 40, 50, and 60 ms. Accuracy ±5ms	Based on frequency of 20 to 45 Hz in 5 Hz steps	Based on frequency of 20 to 60 Hz in 5 Hz steps	Time adjustable in following discrete steps: 30, 40, 50, and 60 ms. Accuracy ±5ms	Identical
Stimulation Trigger Source (When used for gait)	Tilt Sensor or Foot Sensor	Foot Sensor	Foot Sensor	Tilt Sensor or Foot Sensor	Identical
Tilt Detection	Tilt angles between -15 and 35 degrees are capable of being detected by the tilt sensor.	No	No	Tilt angles between -15 and 35 degrees are capable of being detected by the tilt sensor.	Identical
Burst (exercise) Mode (Y/N Pulses/burst Burst/sec Burst duration Duty cycle	Yes Burst length and pps dependent Depends on ON and OFF times 1 to 5 sec in 1 sec steps Depends on ON and OFF times	Yes Burst length and pps dependent Depends on ON and OFF times 4 to 20 sec in 1 sec steps Depends on ON and OFF times	Yes Burst length and pps dependent Depends on ON and OFF times 1 to 10 sec in 1 sec steps Depends on ON and OFF times	Yes Burst length and pps dependent Depends on ON and OFF times 1 to 5 sec in 1 sec steps Depends on ON and OFF times	Identical

FEATURE	INNOVATIVE NEUROTRONICS, INC. WALKAIDE K052329	BIONESS L300 PLUS K103343	ODSTOCK PACE K102115	INNOVATIVE NEUROTRONICS, INC. WALKAIDE PROPOSED K123972	COMPARISON
Stimulation duration when used for gait	Dependent on length and speed of stride <3 sec Max settable from 0.1 to 3 seconds, 0.1 second resolution	Max settable from 2 to 10 seconds, 1 second resolution	Max settable from 0.3 to 6 seconds ±10% in 50 ms steps	Dependent on length and speed of stride Max settable from 0.1 to 3 seconds, 0.1 second resolution	Identical
Max. Burst Duration (Seconds)	<5 exercise mode	10	6	<5 exercise mode	
Timer Range (in exercise mode)					Identical
ON Time	1 to 5 sec in 1 sec steps	4 to 20 sec in 1 sec steps	1 to 10 sec in 1 sec steps	1 to 5 sec in 1 sec steps	
Off Time	1 to 10 sec in 1 sec steps	4 to 60 sec in 1 sec steps	1 to 10 sec in 1 sec steps	1 to 10 sec in 1 sec steps	
Total Duration	1 to 30 min in 1 min steps	5 to 60 min in 5 min steps	5 to 100 min in 5 min steps	1 to 30 min in 1 min steps	
Max Phase Charge:					Equivalent
500 Ohms:	24 microCoulombs	24.0 microCoulombs measured	41 microCoulombs measured	41.2 microCoulombs measured	
1K Ohms:	17 microCoulombs	24.5 microCoulombs measured	30 microCoulombs measured	28.0 microCoulombs measured	

Maximum RMS Current Density **(Computed limit of 6.32 mA rms/cm^2 based on IEC 60601-2-10 max current limit of 50 mA rms)**	1.39 mA rms/cm^2 max (Computed based on square pulse) 1.1 mA rms/cm^2 measured	0.83 mA rms/cm^2 max (Computed based on 80 mA square pulse) 0.82 mA rms/cm^2 measured	1.03 mA rms/cm^2 max (Computed based on 176 mA square pulse) 0.82 mA rms/cm^2 measured	2.62 mA rms/cm^2 max (Computed based on square pulse) 1.80 mA rms/cm^2 measured **(Computed limit of 6.32 mA rms/cm^2 based on IEC 60601-2-10 max current limit of 50 mA rms)**	Equivalent
Max. Average Power Densit **(FDA "Guidance Documer for Powered Muscle Stimulator 510(k)s" June 9, 1999 max limit of 0.25 Watts/cm^2)** **(Computed limit of 0.16 Watts/cm^2 based on IEC 60601-2-10 max current limit of 50 mA rms)**	0.012 Watts/cm^2 (Using 500 Ohm) 0.00490 Watts/cm^2 @ 500Ω measured	0.00536 Watts/cm^2 @ 500Ω measured	0.00848 Watts/cm^2 @ 500Ω measured	0.027 Watts/cm^2 max @ 500 ohms (Computed based on square pulse) 0.0128 Watts/cm^2 @ 500Ω Measured **(FDA "Guidance Document for Powered Muscle Stimulator 510(k)s" June 9, 1999 max limit of 0.25 Watts/cm^2)**	Equivalent
Electrode Size and Shape (Smallest recommended)	3.175 cm (1.25 inches) diameter Round	45mm diameter Round	50 mm x 50 mm Square	3.175 cm (1.25 inches) diameter Round	Identical
Electrode material (Basic mechanical element) Material contacting skin	Hydrogel and Stainless Steel (SS) 316	Hydrogel	Hydrogel and Stainless Steel	Hydrogel and Stainless Steel (SS) 316	Identical
Housing Material	ABS	Unknown	Unknown	ABS	Identical
Shipping and storage Operating	Temp: -20 to +60 degrees C Relative Humidity: 95% max, non-condensing Temp: 0-40 degrees C Altitude: from -400 to 2,400 meters (-1300 to 8,000 ft) Relative Humidity: 0 to 95%, non-condensing	Temp:-20° to 70° C Humidity: 25% to 85% Atmospheric Pressure: 900hPa to 1060hPa Temp: 5° to 40° C Humidity: 25% to 85% Atmospheric Pressure: 900hPa to 1060hPa	Temp: 0° to 40° C Humidity: 35% to 50% Temp: 5° to 27° C Humidity: 35% to 50%	Temp: -20 to +60 degrees C Relative Humidity: 95% max, non-condensing Temp: 0-40 degrees C Altitude: from -400 to 2,400 meters (-1300 to 8,000 ft) Relative Humidity: 0 to 95%, non-condensing	Identical
Auto Overload Trip	No	No	No	No	Identical
Auto No-load Trip	No	No	No	No	Identical
Auto Shutoff	No	No	Yes, after 4 hours in standby	No	Identical

Patient Override Control	Manual amplitude Control Knob	Intensity adjustment buttons and ON/OFF button	Amplitude control knob and pause button	Manual amplitude Control Knob	Identical
Voltage/Current Level Indicator	Yes	Yes	Yes	Yes	Identical
Weight	4 oz including battery	Control Unit 45 gm RF Stim Unit 50 gm Gait Sensor 35 gm	112gm including battery	4 oz including battery	Identical
Dimensions	2.4"x3.25"x0.81"	Control Unit 71x46x17.5mm RF Stim Unit 74x43x15mm Gait Sensor 80x50x10mm	72 x 62 x 26 mm	2.4"x3.25"x0.81"	Identical
Compliance with Voluntary Standards	IEC 60601-1 2nd Ed	IEC 60601-1:2003	ISO 60601-1-1:2006	IEC 60601-1 3rd Ed	Identical
	IEC 60601-1-2:2001		ISO 60601-1-2:2007	IEC 60601-1-2:2007	
	IEC 60601-2-10:1987+A1	IEC 60601-2-10:1987+A1	ISO 60601-2-10:2001	IEC 60601-2-10:1987+A1	
Compliance with 21 CFR 898	Yes	Unknown	Unknown	Yes	Identical

Sample Calculations

- Maximum RMS Output Current at 500 ohms

  Assume a square pulse of height H, width W, Frequency F, load resistance R, and electrode area A:
  $Irms = \sqrt{((H/R)^2 \cdot W \cdot F)} = \sqrt{((103.4/500)^2 \cdot (300e\text{-}6) \cdot 33.3)} = 20.7$ mA rms

- Maximum RMS Current Density at 500 ohms

  $Imax_{rms} = Irms/A = 20.7/7.9cm^2 = 2.62$ mA rms/ cm^2

- Maximum Average Power Density at 500 ohms

  $Pavg = I^2R \cdot W \cdot F/A = (H/R)^2 * R * W \cdot F/A = (103.4/500)^2 \cdot 500 \cdot (300e\text{-}6) \cdot 33.3/7.9cm^2 = 0.027$ Watts/ cm^2

- Max RMS Current Density based on IEC 60601-2-10 limit of 50 mA RMS

  $Irms_{rms} = 50$ mA rms/electrode area = 50 mA rms/$7.917cm^2 = 6.32$ mA rms/cm^2

- Max RMS Current Density based on FDA "Guidance Document for Powered Muscle Stimulator 510(k)s" June 9, 1999 limit of 0.25 Watts/cm^2

  $Irms_{rms} = (\sqrt{0.25}$ Watts/$cm^2 * A/R)/A = (\sqrt{0.25}$ Watts/$cm^2 * 7.917/500)/7.917 = 7.95$ mA rms/cm^2

- Max Average Power Density based on IEC 60601-2-10 limit of 50 mA RMS (0.05A rms)

  $Pavg = I^2 * R/A = .05 * .05 * 500/7.917$ $cm^2 = 0.16$ Watts/cm^2

Discussion of Table 6.1 equivalent parameters

Output Stage

The Constant Voltage output (Adjustable) is 0 – 110 Volts (±10%) compared to the parent at 0 – 78 Volts (±5%) at 1000 Ohms load. The proposed output voltage is within the range of the Bioness (K103343) approved device which has an output of 120 volts. The Odstock Pace (K102115) delivers up to 100mA +/- 10% into 1000 ohms, which equates to an output voltage of 100 +/-10% Volts. The output of the proposed device is within the range of the Bioness device.

Maximum Output Current

The specification peak output current of the proposed device at 500 ohms is 206.8 mA compared to 120.8 mA for the parent device and at 1000 ohms it is 121 mA compared to 78 mA. For comparison purposes there are no equivalent parameters provided by the competitive devices; however, measured peak current at 500 ohms of the Bioness device is 80 mA and the Odstock device is 176 mA. These peak values do not accurately reflect the effective current, or actual energy delivered to the patient, of the devices since, particularly for the proposed, parent, and Odstock devices, the waveforms are not a simple square wave. In the case of the proposed device the output voltage rapidly rises to the peak value at the start of the stim pulse then gradually slopes downward – for instance, at the end of a 300µs pulse the current is approximately 45% of the peak value (refer to waveforms in tab 14. As an example, the same peak current value would be measured for a waveform that maintains a constant current of 100mA for the duration of the stim pulse and a waveform that has a current of 10 mA for 95% of the pulse with a transient of 100mA for the remaining 5%. These two waveforms would, however, deliver substantially different levels of energy to the patient.

A much more important measure of the effectiveness of the output current in delivering energy to the patient is the rms current level. The rms current level takes into account the actual waveform shape and duty cycle. In the Max Current Section of following table the bold values list the measured rms current levels for the four devices and should be used for a more accurate comparison of the maximum effective energy transferred to the

patient. The measured rms current level for the proposed device at 500 ohms is 14.2 mA rms, as compared to 20.6 mA rms for the Odstock device and 13.1 mA rms for the Bioness device. The rms current level for the proposed device is **actually less than the Odstock device** and in the same range as the Bioness device. These levels meet the 50 mA rms limit specified in paragraph 51.104 of IEC 60601-2-10. The modification does not raise any safety or effectiveness issues since it meets the applicable requirements of IEC 60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators." V012 " WalkAide Performance Test Protocol" tests to the applicable requirements of IEC 60601-2-10

Maximum Output Voltage

The Max Output Voltage (baseline to peak; load) is 121 Volts at 1000 Ohms load compared to the parent device at 78 Volts at 1000 ohms load. The waveforms of the parent and proposed devices have the characteristic of rapidly rising to the peak value then gradually decreasing to a significantly lower value at the end of the pulse. The proposed device Max Output Voltage of 121 Volts at 1000 ohms is within <1% of the Bioness (K103343) approved device which has a stated output maximum of 120 volts. There is no stated tolerance on the Bioness voltage specification. With a 1 megohm load the specified maximum output voltage of the proposed device is less than 150V with a measured maximum of 123V while the measured maximum of the Odstock device is 150V.

On Ramp and OFF Ramp

The ON Ramp and OFF Ramp features have been added to the proposed device. The ON Ramp Feature has been added to optionally help with patient muscle spasticity (tone) or rapid toe lift during onset of stimulation during the patient gait cycle. During the Ramp Up time the intensity of the stimulation pulse is gradually increased over the first few seconds of stimulation. OFF Ramp has been added to optionally help with patient toe slap at the end of stimulation in the patient gait cycle. During the Ramp Down time, the intensity of the stimulation pulses in gradually decreased at the end of stimulation in the patient gait cycle. The ON Ramp and OFF Ramp features of the proposed device are equivalent to the ON Ramp and OFF Ramp features in the Bioness L300 Plus (K103343) and the Odstock Pace (K102115).

Pulse Duration

The proposed Pulse Duration is 25-300 microseconds ± 5% (Adjustable)

compared to the parent device of 50-250 microseconds ± 5% (Adjustable). The proposed maximum pulse duration at 300 microseconds is equal to or less than other approved devices (Bioness at 300 microseconds and Odstock at 360 microseconds). The proposed minimum pulse duration of 25 microseconds is within the range of the Odstock at 0 - 360 microseconds. This is equivalent to the predicate devices.

Frequency Range

The proposed device and the parent device output pulse frequency range is selectable between 16.7, 20, 25, and 33.3 pps. The Bioness device range is selectable from 20 to 45 pps in 5 pps steps and the Odstock is selectable from 20 to 60 pps in 5 pps steps. The proposed device is identical to the parent device and is essentially equivalent to the other predicate devices.

Maximum Phase Charge

The measured Maximum Phase Charge at 500 ohms load is 41.2 MicroCoulombs (μC) compared to 24 μC for the parent device, and at 1000 ohms load is 28 μC compared to 17 μC. The maximum phase charge of 41.2 μC for the proposed device is significantly lower than the maximum safety limit of 75 μC specified in paragraph 3.2.2.2 of ANSI/AAMI NS4-1985, "American National Standard for Transcutaneous Electrical Nerve Stimulators." For comparison purposes there are no equivalent parameters provided by the competitive devices. However, the measured phase charge of the Odstock device at 500 ohms is 41 μC as compared to the proposed device of 41.2 μC. At 1000 ohms the measured values are 30 and 28 μC, respectively. The measured phase charge for the proposed device is equivalent to that of the Odstock device. The modification does not raise any safety or effectiveness.

Maximum RMS Current Density

The measured Maximum RMS Current Density of the proposed device is 1.80 mA rms/cm^2, compared to the Odstock and Bioness devices both with 0.82 mA rms/cm^2 and the parent device at 1.1 mA rms/cm^2. There are no specific requirements for the Maximum RMS Current Density in IEC 60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators". Paragraph 51.104 of IEC 60601-2-10 specifies a maximum rms output current level of 50 mA. Using this 50 mA rms maximum current the

maximum allowable current density for the proposed device is 6.32 mA rms/cm^2, as compared to the measured value of 1.80 mA rms/cm^2. In addition, the Maximum RMS Current Density is directly related to the Maximum Average Power Density discussed in the next paragraph. Using the 0.25 Watts/cm^2 limit of the FDA document "Guidance Document for Powered Muscle Stimulator 510(k)s" June 9, 1999 the Maximum RMS Current Density allowable under this limit for the proposed device can be computed as 7.95 mA rms/cm^2. The modification does not raise any safety or effectiveness issues since it meets the applicable requirements of IEC 60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators." V012 " WalkAide. Performance Test Protocol" tests to the applicable requirements of IEC 60601-2-10

Maximum Average Power Density

The Maximum Average Power Density at 500 ohms load for the proposed device is computed to be 0.027 Watts/cm^2 compared to 0.012 Watts/cm^2 for the parent device. These levels were computed assuming a square pulse which, as discussed previously, is not representative of the actual pulse shape or pulse energy. For comparison purposes there are no equivalent parameters provided by the competitive devices. Power density levels for the proposed, Odstock, and Bioness devices using measured rms current levels and stated electrode sizes are 0.0128, 0.0848, and 0.0536 Watts/cm^2, respectively. The FDA document "Guidance Document for Powered Muscle Stimulator 510(k)s" June 9, 1999, states in Section 3 that the maximum power density should be under 0.25 Watts/cm^2. The measured power density of the proposed device is over an order of magnitude under this limit. The modification does not raise any safety or effectiveness issues.

Summary

The proposed WalkAide device meets the applicable clauses of IEC 60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators."

These modifications do not raise any safety or effectiveness issues.

7. CONCLUSIONS

There are basically three changes in Output Specification between the parent WalkAide (K052329) device and the proposed WalkAide (K123972) device: 1) output voltage, 2) output pulse width, and 3) addition of Ramp Modulation (Ramp Up and Ramp Down).

The Output Specifications of the proposed device and the parent device are substantially equivalent. The changes to the output voltage and output pulse width are equivalent to the Bioness and Odstock competitive devices and also still meet the applicable clauses of IEC 60601-2-10 "Particular Requirements for the Safety of Nerve and Muscle Stimulators". V012 " WalkAide Performance Test Protocol" tests to the applicable requirements of IEC 60601-2-10. The addition of Ramp Up and Ramp Down is equivalent to the ramping of the Bioness and Odstock devices.

Based on the above information regarding the equivalent intended use and similar technological characteristics, Innovative Neurotronics believes that the proposed WalkAide is substantially equivalent to the parent WalkAide. The modifications do not raise any safety or effectiveness issues and meet the applicable requirements of IEC 60601-2-10 "Particular requirements for the safety of nerve and muscle stimulators." We conclude that, based on the information above and the Comparison chart below, the proposed Innovative Neurotronics WalkAide System (K123972) is substantially equivalent to the parent Innovative Neurotronics WalkAide System (K052329), the Bioness L300 Plus (K103343), and the Odstock Pace (K102115).

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

April 1, 2013

Innovative Neurotronics, Inc.
c/o Mr. Glen Neally
3600-B North Capital of Texas Highway
Suite 150
Austin, Texas 78746-3211

Re: K123972
Trade/Device Name: WalkAide System
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: March 13, 3013
Received: March 19, 2013

Dear Mr. Neally:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Joyce M. Whang

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number : K123972

Device Name: Innovative Neurotronics, Inc., WalkAide External Functional Neuromuscular Stimulator

Indications for Use:

The Innovative Neurotronics WalkAide External Functional Neuromuscular Stimulator (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 gait, the WalkAide System electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/ retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

Division of Neurological and
Physical Medicine Devices
510(k) Number: K123972