February 14, 2022

Cionic
Mihai Ionescu
Head of Hardware Development
1606 Stockton St, Suite #1
San Francisco, California 94133

Re: K213622
Trade/Device Name: Cionic Neural Sleeve NS-100
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: November 15, 2021
Received: November 16, 2021

Dear Mihai Ionescu:

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,

Amber Ballard, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213622

Device Name
Cionic Neural Sleeve NS-100

Indications for Use *(Describe)*
The Cionic Neural Sleeve NS-100 is intended to provide ankle dorsiflexion and/or plantarflexion in adult 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 Cionic Neural Sleeve NS-100 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The Cionic Neural Sleeve NS-100 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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CIONIC

510(K) Summary

I SUBMITTER

Cionic, Inc.
1606 Stockton St.
Suite #1
San Francisco, CA 94133

Contact Person: Mihai Ionescu
Date Prepared: February 11, 2021

II PROPOSED DEVICE

Trade / Device Name: Cionic Neural Sleeve NS-100
Manufacturer: Cionic Inc.
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
510(k) Number: K213622

III PREDICATE DEVICE

Device Name: L300 Go System
Manufacturer: Bioness Inc.
510(k) Number: K190285

REFERENCE DEVICE

Device Name: Stiwell MED4
Manufacturer: Otto Bock Healthcare Product GmbH
510(k) Number: K080950

IV DEVICE DESCRIPTION

The Cionic Neural Sleeve NS-100 is a platform for the measurement and augmentation of lower limb mobility composed of a body-worn legging, a battery-powered electronic controller and a mobile application. The Cionic Neural Sleeve NS-100 has embedded sensors to measure limb movement and muscle activity. These data are used by the control unit to generate stimulation intended to activate muscles for exercise or functional assistance.

The Cionic Neural Sleeve NS-100 is intended to provide ankle dorsiflexion and/or plantarflexion in adult 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 Cionic Neural Sleeve NS-100 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The Cionic Neural Sleeve NS-100 system sales carton consists of the following components:

1) SL-100 a fabric sleeve covering the upper and lower leg containing embedded motion sensors and skin-contacting electrodes. Left and right leg sleeves are available in two sizes: small, and medium.
2) DC-100 a portable battery-powered Control and Stimulation Unit that connects to, and is worn within the SL-100. The DC-100 communicates over Bluetooth™Low Energy protocol to the Cionic mobile application ("Cionic app").
3) Power supply and cable to recharge the DC-100 and connect the DC-100 to a user's computer when required.
4) Adhesive, electrically conductive and replaceable electrode pads.
5) Electrode cover sheets.
6) Instructions for Use documents.

Components are available as accessories to the Cionic Neural Sleeve NS-100 system:

- Replacement electrode pads.

The Cionic Neural Sleeve NS-100 requires a password-protected Cionic mobile application that is exclusively available to Cionic Neural Sleeve NS-100 users.

The Cionic Neural Sleeve NS-100 system consists of a software and hardware architecture that enables users to access a library exercise and augmentation programs. Programs can be added and removed from the user's mobile app. All exercise and assistance programs utilize a standard calibration and stimulation user interface that is extendible to future exercise and augmentation programs.

V INDICATIONS FOR USE

The Cionic Neural Sleeve NS-100 is intended to provide ankle dorsiflexion and/or plantarflexion in adult 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 Cionic Neural Sleeve NS-100 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The Cionic Neural Sleeve NS-100 may also:

- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

VI COMPARISON OF INDICATIONS FOR USE

The Cionic Neural Sleeve NS-100 Indications for use differs from the Bioness L300 Go System in that the Neural Sleeve can provide plantar flexion of the foot in addition to dorsiflexion of the foot. Adult individuals with muscle weakness related to upper motor neuron disease/injury may have mobility that is limited by insufficient foot plantarflexion, which is unaddressed by the Bioness L300 Go System. Stimulation of the muscles responsible for foot plantarflexion under the same technological characteristics of the predicate device does not pose new issues of safety and effectiveness under the intended use.

Like the Bioness L300 Go, the Neural Sleeve System is intended for adult individuals. Unlike the Bioness L300 Go, the Neural Sleeve System is not intended for pediatric individuals.

VII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Characteristic	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	SUBSTANTIAL EQUIVALENCE
510(k) Number	K213622	K190285	K080950	
Device Name, Model	NS-100	L300 Go System	Stiwell MED4	
Manufacturer	Cionic Inc.	Bioness Inc.	Otto Bock Healthcare Product GmbH	
Product code	IPF, GZI	GZI & IPF	IPF, GZI, GZJ, HCC, KPI	Same as predicate, and a subset of the reference device.
Intended Use / Indications for Use	The Cionic Neural Sleeve NS-100 is intended to provide ankle dorsiflexion and/or plantarflexion in adult 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 Cionic Neural Sleeve NS-100 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.	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;	The STIWELL MED4 is a neuromuscular electrical stimulator indicated for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a powered muscle stimulator STIWELL MED4 is indicated for the following conditions: • Relaxation of muscle spasm • Prevention of retardation of disuse atrophy • Increasing local blood circulation •	Same as predicate, and a subset of the reference device.

	The Cionic Neural Sleeve NS-100 may also: • Facilitate muscle re-education • Precent/retard disuse atrophy • Maintain or increase joint range of motion • Increase local blood flow	thus, it also may improve the individual's gait. The L300 Go System may also: • Facilitate muscle re-education • Precent/retard disuse atrophy • Maintain or increase joint range of motion • Increase local blood flow	• Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Maintaining or increasing range of motion As a transcutaneous electrical nerve stimulator for pain relief the STIWELL MED4 is indicated for the following conditions: • Symptomatic relief and management of chronic (long-term) intractable pain • Adjunctive treatment in the management of post-surgical pain and post traumatic acute pain As a biofeedback device the STIWELL MED4 is indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes As an external functional neuromuscular stimulator the STIWELL MED4 is indicated for the following conditions:	

			• Helps relearn voluntary motor functions of the extremities	
Number of Output Modes	1 mode: Monophasic with hybrid stimulation	2 modes: Biphasic Asymmetric and Symmetric	One	Substantially equivalent. Differences are considered minor with no impact to safety and effectiveness since mode number of subject device is subset of predicate device.
Number of Program Modes	• Gait Assist • Training/Exercise	• • Gait • Training/Exercise • Cycle Training Mode • Clinician mode	Multiple	Same as predicate device and a subset of reference device.
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Regulated Current	Same
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	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	Battery Pack Li-Ion 11.1V	Substantially equivalent. All three devices meet electrical safety standards. The battery of the proposed device meets IEC 62133-2, Edition 1.0, 2017-02 (also an FDA recognized standard). Differences are considered minor with no impact to safety and effectiveness since all three devices adhere to recognized/consensus electrical/battery safety standards.
Microprocessor - Controlled	Yes	Yes	Yes	Same
Maximum Output Current (+/- 10%) [mA]	Lower leg and thigh: 100 mA @ 500 Ω 60 mA @ 2 kΩ 13 mA @ 10 kΩ Irms=24.6 mA computed based on 500 Ω 100mA (+/- 10%) 400 [µs] 125 Hz	Lower leg: 100mA @ 500 Ω 65mA @ 2 kΩ 13mA @ 10 kΩ Thigh: 100mA @ 500 Ω 65mA @ 2 kΩ 13mA @ 10 kΩ	NMES/TENS/FES 100 mA @ 500 Ω 58 mA @ 2 kΩ N/A mA @ 10 kΩ	Substantially equivalent. Differences are considered minor with no impact to safety and effectiveness since all three devices adhere to recognized/consensus electrical safety standards and all devices are similar within range.

Maximum Current (RMS) Density [mA/cm2]	0.98 mA/cm^2 Irms=24.6 mA computed based on 500 Ω 100mA (+/- 10%) 400 [µs] 125 Hz electrode area of 25cm^2	Thigh EPG: 0.18 mArms/cm2 (500 Ω, Irms=13.0 mA, electrode area of 74 cm2) Lower Leg EPG:	12.5 mA/cm2	Substantially equivalent. Differences are considered minor with no impact to safety and effectiveness since all three devices adhere to recognized/consensus

		small cuff, gel electrodes 1.27 mArms/cm2 (500 Ω, Irms=13.0 mA, electrode area of 10.2 cm2)		electrical safety standards and all devices are similar within range.
Maximum Power Density [mW/cm2]	12mW/cm2 (500 Ω, Irms=24.6 mA, electrode area of 25 cm2)	Thigh EPG: 1.1 mW/cm2 (500 Ω, Irms=13.0 mA, electrode area of 74 cm2) Lower Leg EPG: small cuff, gel electrodes 8.3 mW/cm2 (500 Ω, Irms=13.0 mA, electrode area of 10.2 cm2) regular cuff, gel electrodes 5.3 mW/cm2 (500 Ω, Irms=13.0 mA, electrode area of 15.9 cm2)	7.9mW/cm2	Substantially equivalent. Differences are considered minor with no impact to safety and effectiveness since all three devices adhere to recognized/consensus electrical safety standards and all devices are similar within range.
Stimulation Channels	1 stimulator channel with 8 virtual Positive output channels and 15 virtual Negative 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	3 for FES programs 1 for Incontinence programs 4 for TENS programs 1 for Biofeedback	Substantially equivalent. The proposed device contains a subset of the number of channels available on the predicate and reference devices. Differences are considered minor with no impact to safety and effectiveness since proposed device stimulation channels are a subset of predicate and reference devices.
Connection of device electrodes	24 Hydrogel electrode pads adhesively connected to non-tissue contacting electrode bases.	Lower Leg FSC: • 2 Hydro-Gel electrodes assembled on electrode bases, or • 2 non-woven cloth electrodes assembled on electrode bases, or	Not Publicly Available	Substantially equivalent. Electrode pads used in the proposed and predicate devices attach using similar methods, and both devices embed the electrode wires. The reference device uses standard electrode pads and leads. Differences are considered minor with no

		• 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		impact to safety and effectiveness since proposed device connection of electrodes is similar to predicate and reference devices.
Clinician Control/ Programming	No separate clinician programming mode.	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.	Not Publicly Available	Substantially equivalent. Differences are considered minor with no impact to safety and effectiveness since the proposed device still provides clinician control as in the predicate and reference device, just not in the same specific technological manner. Proposed device enables clinician control through a web/internet interface which was successfully verified/validated during development.
User Control	Using the Cionic mobile app, the user can: • Start/Stop stimulation • Modulate stimulation between 0 and 100% • Fine tune stimulation intensity around the working point set by Cionic technician. • Select Assist/Exercise program	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	Not Publicly Available	Substantially equivalent. Differences are considered minor with no impact to safety and effectiveness since the proposed device still provides user control as in the predicate and reference device, just not in the same specific technological manner. Proposed device enables user control through a mobile app interface which was successfully verified/validated during development.

	• Test stimulation before starting an Assist/Exercise program Using the hand-held Control Unit worn within the Neural Sleeve, the user can: • Turn Control Unit On/Off • Reset Control Unit to factory settings • Pause and unpause stimulation	working point set by the clinician • Test L300 Lower Leg EPG & Thigh EPG stimulation before starting to ambulate		
Stimulation Trigger Source for Gait Assist	In gait mode, stimulation is triggered by the two IMUs (Inertial Measurement Unit) embedded in the SL-100, one on the shank and the other on the thigh. In EMG exercise mode, stimulation is triggered by the EMG sensors embedded in the SL-100.	In gait mode, stimulation is triggered by: (1) the motion sensor embedded in the EPG (two-dimension tilt); or (2) Foot Sensor that detects Heel On & Heel Contact events during gait and transmits them wirelessly to the lower and thigh EPGs.	N/A	Substantially equivalent to the predicate device. The manner in which both devices enable stimulation are different, however the difference is considered minor (therefore no impact to safety/effectiveness) due to the fact that both methods of enabling stimulation are based on detecting limb motion through motion sensors (Bioness) and IMUs (Cionic). Motion sensors and IMUs are very similar technologies used to measure motion.
Communication Method	DC-100 to SL-100 using a 40-pin connector Mobile Application - Control Unit: wireless Bluetooth (Low Energy) communication protocol Portal - Control Unit (as needed for firmware updates or data transfer): USB-C connector	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)	Not publicly available	Same as predicate.

		communication protocol MAPP- Lower Leg/Thigh EPG: wireless Bluetooth (Low Energy) communication protocol		
Number of EMG (input) Channels	8	N/A	2	Substantially equivalent to reference device. Differences considered minor (therefore no impact to safety and effectiveness) since both devices measure muscle activity via EMG by detecting the electrical signal during activity.
EMG detection (Bipolar/Monopolar)	Bipolar	N/A	Bipolar	Same as reference device
Weight	Control Unit DC-100 145 g Sleeve SL-100 Medium L/R 240 g Sleeve SL-100 Small L/R 230 g	Not Publicly Available	440 g	Substantially equivalent. Although the appearance, weight and dimensions are different between the proposed, predicate, and reference devices, these differences are insignificant and do not raise any issues related to safety and effectiveness.
Dimensions [W x H x D]	DC-100 137 x 53 x 24 mm SL-100 Medium 613 x 602 mm SL-100 Small 596 x 560 mm	Not Publicly Available	Device: 175 x 95 x 30 mm	

VIII PERFORMANCE DATA

Summary of Nonclinical performance testing

The tests listed have been conducted to demonstrate that the Cionic Neural Sleeve performs as intended and is substantially equivalent to the predicate device.

- Stimulation Output Waveforms
- Biological evaluation of medical devices according to ISO 10993-1
- Stimulation Output Specifications
- Stimulation Virtual Output Channels
- Stimulation Output Channel Isolation
- Hybrid Stimulation
- Stimulation Electrodes Short and/or Open detection
- Wireless Coexistence
- Electrical Safety according to IEC 60601-1; IEC 60601-1-11
- Muscle and Nerve Stimulators according to IEC 60601-2-10
- Electromagnetic compatibility according to IEC 60601-1-2
- Usability according to IEC 62366; IEC 60601-1-6
- Software validation according to IEC 62304

IX CONCLUSION

The Cionic Neural Sleeve NS-100 has been verified and validated successfully for its intended use through a combination of original bench testing and verification and validation of all software and firmware. Based on the result of the nonclinical testing, Cionic concludes that the device is substantially equivalent to the predicate Bioness L300 Go System.