July 21, 2022

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

Re: K221823
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

Dear Mihai Ionescu:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 21, 2022. Specifically, FDA is updating this SE Letter to include a secondary product code, IPF, in addition to the primary product code, GZI, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Amber Ballard, PhD, OHT5: Office of Neurological and Physical Medicine Devices, Assistant Director, Amber.Ballard@fda.hhs.gov.

Sincerely,

Lauren E. Woodard -S

for 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

July 21, 2022

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

Re: K221823
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
Dated: June 22, 2022
Received: June 23, 2022

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
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and Physical Medicine Devices
Office of Product Evaluation and Quality
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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)*
K221823

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

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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: July 19, 2022

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: K221823

III REASON FOR SUBMISSION

The reason for this submission is to add compatibility of the Cionic Neural Sleeve to support the Android operating system. Other design changes which are considered minor have been implemented to the subject device since the original K213622 clearance. These changes are minor software updates which were implemented to improve the application's overall stability and performance.

IV TYPE OF SUBMISSION

Special 510(k)

V PREDICATE DEVICE

Device Name: Cionic Neural Sleeve NS-100
Manufacturer: Cionic, Inc.
510(k) Number: K213622

VI PURPOSE OF THIS SPECIAL 510(k)

This Special 510(k) is submitted to add an Android version Mobile Application to the Cionic Neural Sleeve NS-100 as well as to include minor modifications made to the device software since the clearance of the last 510(k), K213622. None of these changes affect the intended use of the device nor do they alter the fundamental scientific technology of the device.

VII 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 iOS and Android 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.

VIII 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

IX MODIFICATIONS ADDRESSED IN THIS SPECIAL 510(k)

This Special 510(k) addresses the following modifications:

- Changes to the Mobile Application iOS software
- Changes to the Device software and firmware
- Changes to the Technician Web Portal
- Changes to the Cionic Cloud APIs
- Labeling Changes
- Addition of an Android version Mobile Application

X COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

CHARACTERISTIC	SUBJECT DEVICE	PREDICATE DEVICE (K213622)	SUBSTANTIAL EQUIVALENCE
510(k) Number	K221823	K213622	
Device Name, Model	NS-100	NS-100	Same
Manufacturer	Cionic Inc.	Cionic Inc.	Same
Product code	IPF, GZI	IPF, GZI	Same
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 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	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 • Precent/retard disuse atrophy • Maintain or increase joint range of motion • Increase local blood flow	Same
Number of Output Modes	1 mode: Monophasic with hybrid stimulation	1 mode: Monophasic with hybrid stimulation	Same

Number of Program Modes	• Gait Assist • Training/Exercise	• Gait Assist • Training/Exercise	Same
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Same
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Same
Microprocessor-Controlled	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 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	Same
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	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	Same
Maximum Power Density [mW/cm2]	12mW/cm2 (500 Ω, Irms=24.6mA, electrode area of 25 cm2)	12mW/cm2 (500 Ω, Irms=24.6mA, electrode area of 25 cm2)	Same
Stimulation Channels	1 stimulator channel with 8 virtual Positive output channels and 15 virtual Negative output channels	1 stimulator channel with 8 virtual Positive output channels and 15 virtual Negative output channels	Same
Connection of device electrodes	24 Hydrogel electrode pads adhesively connected to non-tissue contacting electrode bases	24 Hydrogel electrode pads adhesively connected to non- tissue contacting electrode bases	Same
Clinician Control/ Programming	No separate clinician programming mode	No separate clinician programming mode	Same
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 • 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	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 • 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	Same

	• Pause and unpause stimulation	• Pause and unpause stimulation	
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 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	Same
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	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	Same
EMG detection (Bipolar/Monopolar)	Bipolar	Bipolar	Same
Weight	Control Unit DC-100 145 g Sleeve SL-100 Medium L/R 240 g Sleeve SL-100 Small L/R 230 g	Control Unit DC-100 145 g Sleeve SL-100 Medium L/R 240 g Sleeve SL-100 Small L/R 230 g	Same
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	DC-100 137 x 53 x 24 mm SL-100 Medium 613 x 602 mm SL-100 Small 596 x 560 mm	Same
Mobile Application OS Compatibility	Android, iOS	iOS	Different - added Android compatibility; risk analysis and testing demonstrate SE

XI PERFORMANCE DATA

Software and Firmware changes were subject to verification testing to ensure no loss of original functionality. The tests listed have been conducted to demonstrate that the Cionic Neural Sleeve performs as intended and is substantially equivalent to the predicate device.

- Wireless Coexistence according to FDA Guidance Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: August 14, 2013.
- Software validation according to IEC 62304

The following non-clinical performance tests were leveraged from the predicate device submission because the addition of the Android operating system and the minor software modifications did not affect the following testing areas for the subject 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
- 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

XII 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 Cionic Neural Sleeve.