May 2, 2025

CIONIC Inc.
Mihai Ionescu
EVP Hardware and Manufacturing
1500 Green Hills Road Suite 109
Scotts Valley, California 95066

Re: K243828
Trade/Device Name: Cionic Neural Sleeve (NS-200)
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF, HCC
Dated: March 31, 2025
Received: March 31, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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)*
K243828

Device Name
Cionic Neural Sleeve NS-200

Indications for Use *(Describe)*
The Cionic Neural Sleeve NS-200 is intended to provide ankle dorsiflexion and/or plantarflexion and/or eversion 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-200 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion and/or eversion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The Cionic Neural Sleeve NS-200 may also:
- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

As a powered muscle stimulator the Cionic Neural Sleeve NS-200 is indicated for the following conditions:
- Relaxation of muscle spasm

As a biofeedback device the Cionic Neural Sleeve NS-200 is indicated for the following conditions:
- Biofeedback, relaxation and muscle re-education purposes

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

I SUBMITTER

Cionic, Inc.
1500 Green Hills Road
Suite 109
Scotts Valley, CA 950-66

Contact Person: Mihai Ionescu
Email: mihai@cionic.com
Phone Number: (831) 824-4051
Date Prepared: December 10, 2024

II PROPOSED DEVICE

Trade / Device Name: Neural Sleeve NS-200
Manufacturer: Cionic Inc.
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF, HCC
510(k) Number: K243828

III PREDICATE DEVICES

Primary Predicate Device: Neural Sleeve NS-100
Manufacturer: Cionic Inc.
510(k) Number: K221823

Secondary Predicate Device: STIWELL med4
Manufacturer: Otto Bock Healthcare Product GmbH
510(k) Number: K080950

IV DEVICE DESCRIPTION

General Information
Same as the primary predicate device, the Cionic Neural Sleeve NS-100 (K221823), the Cionic Neural Sleeve NS-200 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-200 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-200 system sales carton consists of the following components:

1) SL-200 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 four sizes: extra-small, small, medium, and large.
2) DC-200 a portable battery-powered Control and Stimulation Unit that connects to, and is worn within the SL-200. The DC-200 communicates over Bluetooth™Low Energy protocol to the Cionic mobile application (“Cionic app”).
3) Power supply and cable to recharge the DC-200 and connect the DC-200 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-200 system:

- Replacement electrode pads.

The Cionic Neural Sleeve NS-200 requires a password-protected Cionic mobile application that is exclusively available to Cionic Neural Sleeve NS-200 iOS and Android users.

The Cionic Neural Sleeve NS-200 system consists of a software and hardware architecture that enables users to access a library exercise and programs. Programs can be added and removed from the user’s mobile app by the user. All exercise and assistance programs utilize a standard calibration and stimulation user interface that is extendible to future exercise and augmentation programs.

The following minor hardware/mechanical changes have been made to the NS-100 (K221823) and incorporate in the NS-200:

1. **Simplified Sleeve Electronics**
   By relocating the electromyography (EMG) circuitry to the Control Unit (DC-200), the redesigned Sleeve (SL-200) is now lighter, more streamlined, and requires less power—delivering a more comfortable and efficient experience for users.
2. **Enhanced Control Unit Grip**
   The Control Unit (DC-200) now features integrated side grips, making it easier to connect and disconnect from the sleeve cable—while maintaining the same compact form factor users love.
3. **More Secure Fit, All Day Comfort**
   Enhanced Velcro sections on the Sleeve (SL-200) offer improved adherence and a more secure fit, supporting confident wear and optimal electrode positioning throughout the day.

New Functionality in NS-200

When compared to the primary predicate device, the Cionic NS-100 (K221823), while maintaining the same hardware architecture, the NS-200 introduces advanced biofeedback

capabilities through software enhancements that leverage the existing surface electromyography (sEMG) functionality. This biofeedback implementation is delivered through two distinct training modes within the existing Exercise Programs:

1. **Visual Biofeedback Mode**
   This mode operates without electrical stimulation, providing real-time visual feedback through the mobile application interface. The user's muscle activation levels are displayed as dynamic intensity bars on the smartphone screen, allowing the user to visualize and modulate the muscle recruitment patterns.
2. **Muscle Activated Stimulation Mode**
   This mode creates a closed loop feedback system where the user's voluntary muscle contractions, detected through sEMG, trigger electrical stimulation when reaching specific thresholds. The stimulation trigger is set at 20% of the maximum activation level recorded during the EMG calibration step.

V INDICATIONS FOR USE

The Cionic Neural Sleeve NS-200 is intended to provide ankle dorsiflexion and/or plantarflexion and/or eversion 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-200 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion and/or eversion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

The Cionic Neural Sleeve NS-200 may also:
- Facilitate muscle re-education
- Prevent/retard disuse atrophy
- Maintain or increase joint range of motion
- Increase local blood flow

As a powered muscle stimulator the Cionic Neural Sleeve NS-200 is indicated for the following conditions:
- Relaxation of muscle spasm

As a biofeedback device the Cionic Neural Sleeve NS-200 is indicated for the following conditions:
- Biofeedback, relaxation and muscle re-education purposes

VI COMPARISON OF INTENDED USE

Table 1. COMPARISON OF INDICATIONS FOR USE

Characteristic	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE

510(k) Number	K243828	K221823	K080950
Device Name, Model	Neural Sleeve NS-200	Neural Sleeve NS-100	STIWELL med4
Manufacturer	Cionic Inc.	Cionic Inc.	Otto Bock Healthcare Product GmbH
Regulation	21 CFR 882.5810	21 CFR 882.5810	21 CFR 890.5850
Product codes	GZI, IPF, HCC	GZI, IPF	IPF, GZJ, HCC, GZI, KPI
Intended Use / Indications for Use	The Cionic Neural Sleeve NS-200 is intended to provide ankle dorsiflexion and/or plantarflexion and/or eversion 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-200 electrically stimulates muscles in the affected leg to provide ankle dorsiflexion and/or plantarflexion and/or eversion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait. The Cionic Neural Sleeve NS-200 may also: ● Facilitate muscle re-education ● Prevent/retard disuse atrophy ● Maintain or increase joint range of motion ● Increase local blood flow As a powered muscle stimulator the Cionic Neural Sleeve NS-200 is indicated for the following conditions: ● Relaxation of muscle spasm As a biofeedback device the Cionic Neural Sleeve NS-200 is indicated for the following conditions: ● Biofeedback, relaxation and muscle re-education purposes	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 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 - 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
Note: Same as the secondary predicate device (STIWELL med4, K080950), Cionic Neural Sleeve NS-200 utilizes EMG biofeedback to achieve muscle relaxation and re-education.			

VII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 2. Functional Electrical Stimulation Modes

Characteristic	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE	SE Comparison
510(k) Number	K243828	K221823	K080950	
Device Name, Model	NS-200	NS-100	STIWELL med4	
Manufacturer	Cionic Inc.	Cionic Inc.	Otto Bock Healthcare Product GmbH	
Regulation	21 CFR 882.5810	21 CFR 882.5810	21 CFR 890.5850	
Product codes	GZI, IPF, HCC	GZI, IPF	IPF, GZJ, HCC, GZI, KPI	
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Battery Pack Li-Ion 11.1V	The subject device's battery is identical to the battery of the primary predicate device and is very similar to the battery of the secondary predicate device. 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 on safety and effectiveness since all three devices adhere to recognized/consensus electrical/battery safety standards.
Method of Line Current Isolation	Medical Class II Power Adapter Input: 100-240V 50/60Hz Output: 5V 2A using USB-C cable	not publicly available	Medical Class II Power Adapter – Mascot (12.6VDC-15.1W)	Differences when compared to the secondary predicate device are considered minor with no impact on safety and effectiveness
Number of Output Modes	1 mode: Monophasic with hybrid stimulation	1 mode: Monophasic with hybrid stimulation	1	The subject device is identical to the primary predicate device.

				Differences when compared to the secondary predicate device are considered minor with no impact on safety and effectiveness
Number of Output Channels	1 stimulator channel with 8 virtual Positive and 15 virtual Negative output channels	1 stimulator channel with 8 virtual Positive and 15 virtual Negative output channels	3	The subject device is identical to the primary predicate device. Compared to the secondary predicate device, the subject device includes fewer physical stimulation channels. However, it achieves the same therapeutic effects and delivers substantially equivalent stimulation by incorporating a 24-channel high-voltage multiplexer (MUX). This MUX functions as an electronic switch that time-shares a single stimulation output across multiple electrodes in rapid succession. Differences are considered minor with no impact on safety and effectiveness.
Stimulated Muscles	Shin (Tibialis Anterior) Quadriceps Calf (Gastrocnemius) Hamstrings	not publicly available	FES 1 (Grasp/Release): Wrist extensors, Finger flexors, Thumb flexor FES 2 (Grasp/Release [EMG]): Wrist extensors, Finger flexors, Thumb flexor FES 3 (Open/Close): Finger/thumb extensors, Finger flexors, Thumb flexor FES 4 (Open/Close [EMG]): Finger/thumb extensors, Finger flexors, Thumb flexor	When compared to the secondary predicate device, although the subject device targets a different set of muscles, both utilize functional electrical stimulation to improve body movements.
Number of EMG (input) Channels	8	Not publicly available	FES 1 (Grasp/Release): 0 FES 2 (Grasp/Release [EMG]): 1 FES 3 (Open/Close): 0 FES 4 (Open/Close [EMG]): 1	When compared to the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.

EMG Sensitivity	0.0298 µV	Not publicly available	FES 1 (Grasp/Release): N/A FES 2 (Grasp/Release [EMG]): 1 µV FES 3 (Open/Close): 0 FES 4 (Open/Close [EMG]): 1 µV	When compared to the FES 2 and FES 4 modes of the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.
EMG Sampling Rate	2kHz	Not publicly available	FES 1 (Grasp/Release): N/A FES 2 (Grasp/Release [EMG]): 3kHz FES 3 (Open/Close): N/A FES 4 (Open/Close [EMG]): 3kHz	When compared to the FES 2 and FES 4 modes of the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.
EMG detection (bipolar/monopolar)	Bipolar	Bipolar	FES 1 (Grasp/Release): N/A FES 2 (Grasp/Release [EMG]): bipolar FES 3 (Open/Close): N/A FES 4 (Open/Close [EMG]): bipolar	Identical to the primary predicate device and the FES 2 and FES 4 modes of the secondary predicate device.
EMG range (µV)	$+/-2.5*10^6$ µV	Not publicly available	FES 1 (Grasp/Release): N/A FES 2 (Grasp/Release [EMG]): 1-2000 µV FES 3 (Open/Close): N/A FES 4 (Open/Close [EMG]): 1-2000 µV	When compared to the FES 2 and FES 4 modes of the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.
EMG bandwidth	10-500 Hz	Not publicly available	FES 1 (Grasp/Release): N/A FES 2 (Grasp/Release [EMG]): 70-480 Hz FES 3 (Open/Close): N/A	When compared to the FES 2 and FES 4 modes of the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.

			FES 4 (Open/Close [EMG]): 70-480 Hz	
EMG signal processing (e.g. RMS)	RMS (Root Mean Square)	Not publicly available	FES 1 (Grasp/Release): N/A FES 2 (Grasp/Release [EMG]): AVR (Average Rectified Value) FES 3 (Open/Close): N/A FES 4 (Open/Close [EMG]): AVR	When compared to the FES 2 and FES 4 modes of the secondary predicate device, differences in EMG signal processing does not lead to questions of safety and effectiveness because both RMS and AVR can be used to quantify the amplitude or magnitude of the EMG signal, providing an estimate of muscle activity
Synchronous or Alternating	Alternating	Not publicly available	Alternating	Identical to the secondary predicate device
Method of Channel Isolation	The virtual output channels are multiplexed through a 24-channel high voltage analog switch with channel isolation of -33 dB (typical), Switch crosstalk of -70 dB (typical) and switch-off leakage current of 1 µA typical per switch	Not publicly available	Transformer, Inductive couplers	When compared to the secondary predicate device, both are using high voltage FET (field-effect transistor) switches. The secondary predicate device uses a different method of isolation, but both methods achieve the same result. This was based on the results of the channel isolation bench test, and the IC manufacturer datasheet
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Regulated Current	Identical to both predicate devices
Software/Firmware Microprocessor Control?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Automatic Overload Trip, No-Load Trip, Shut Off?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Patient Override Control?	Yes (Stop Button)	Not publicly available	Yes (Stop Button)	Identical to the secondary predicate device
Indicator Display On/Off Status?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Indicator Display: Low Batt?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Indicator Display: Voltage Current Level?	Yes	Not publicly available	Yes	Identical to the secondary predicate device

Timer Range (minutes)	Gait mode: (dependent on length and speed of stride) 0-5sec max stimulation duration (user and technician selectable). Exercise mode: 1-60 minutes. EMG triggered stimulation: 1-60 minutes	Not publicly available	15-60 min	When compared to the secondary predicate device, differences in timer range are considered minor since overall intended uses are the same and ultimately achieve the same result i.e., muscle stimulation
Compliance with voluntary Standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Not publicly available	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Identical to the secondary predicate device
Compliance with 21 CFR 898	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Weight	Control Unit (DC-200) 145g Sleeve (SL-200 Left and Right) X-Small (S0) 220g Small (S2) 230g Medium (S4) 240g Large (S6) 250g	DC-100 145 g SL-100 Medium 240g SL-100 Small 230g	440 g	The subject device is identical to the primary predicate device in the weight of the Control Unit, Medium Sleeve, and Small Sleeve. The subject device's sleeve is available in X-small and Large. This difference is insignificant and does not raise any issues of safety and effectiveness. Although the appearance, weight, and dimensions are different between the subject and secondary predicate devices, these differences are insignificant and do not raise any issues related to safety and effectiveness
Dimensions [W x H x D]	Control Unit (DC-200) 136 x 54 x 24 mm Sleeve (SL-200 Left and Right) X-Small (S0) 500 x 600 mm Small (S2) 520 x 610 mm Medium (S4) 580 x 630 mm Large (S6) 690 x 680 mm	DC-100 137 x 53 x 24 mm SL-100 Medium 613 x 602 mm SL-100 Small 596 x 560 mm	Device: 175 x 95 x 30 mm	The subject device's dimension is very similar when compared to the primary predicate device. This difference in dimension is insignificant and does not raise any issues of safety and effectiveness. Although the appearance, weight, and dimensions are different between the subject and secondary predicate devices, these differences are insignificant and do not raise any issues related to safety and effectiveness
Waveform (e.g., pulsed monophasic, biphasic)	Monophasic with hybrid stimulation	Not publicly available	Biphasic Symmetrical	Although the stimulation waveform is different from that of the secondary predicate, the subject device has passed IEC 60601-1 and IEC 60601-2-10,

				so this difference should not affect safety and effectiveness
Shape	Rectangular	Not publicly available	Rectangular	Identical to the secondary predicate
Maximum Output Voltage (+/- 10%) [V]	50V @ 500 Ω 125V @ 2 kΩ 130V @ 10 kΩ	not publicly available	50V @ 500 Ω 115V @ 2 kΩ N/A @ 10 kΩ	Differences between the subject and the secondary predicate devices have no impact on safety and effectiveness since all three devices adhere to recognized consensus and standards and the values are similar within range
Maximum Output Current (+/- 10%) [mA]	100 mA @ 500 Ω 62.5 mA @ 2 kΩ 13 mA @ 10 kΩ Irms=24.6 mA computed based on 500 Ω 100mA (+/- 10%) 400 µs 125 Hz	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	100 mA @ 500 Ω 58 mA @ 2 kΩ N/A @ 10 kΩ Irms: N/A	Differences between the subject and the predicate devices are considered minor and have no impact on safety and effectiveness since all three devices adhere to recognized consensus and standards and the values are similar within range
Pulse width	100, 200, 300, and 400µs Default 300µs	not publicly available	50 to 400 µs	very similar when compared to the secondary predicate device. Although the pulse width ranges are different from that of the secondary predicate, the proposed device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness.
Frequency [Hz]	5 – 125 Hz in 5Hz increment Default 35Hz	not publicly available	1 – 140 Hz Default 35 Hz	very similar when compared to the secondary predicate device. Although the frequency ranges are different from that of the secondary predicate, the proposed device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness.
Net Charge [µC/pulse] (500Ω)	0 µC using Hybrid Stimulation	not publicly available	0 µC Same positive and negative impulse	very similar when compared to the secondary predicate device. Although the method used to achieve 0 µC is different from that of the secondary predicate, the proposed device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness
Maximum Phase Charge[µC] @ 500Ω	40 [µC] @ 500Ω 400 µs * 100 mA = 40 µC	not publicly available	40 [µC] @ 500Ω	Identical to the secondary predicate device

Maximum Current (RMS) Density [mA/cm^2]	1.24 mA/cm^2] Irms=24.6 mA computed based on 500 Ω 100mA (+/- 10%) 400 µs 125 Hz electrode area of 19.8cm^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	12.5 mA/cm^2	The Maximum Current Density of the subject device is very similar when compared to that of the primary predicate device. Differences are considered minor and have no impact on safety and effectiveness since all three devices adhere to recognized consensus
Maximum Power Density [mW/cm^2]	12mW/cm^2 (500 Ω, Irms=24.6 mA, electrode area of 19.8 cm^2)	12mW/cm^2 (500 Ω, Irms=24.6 mA, electrode area of 25 cm^2)	7.9mW/cm2	The subject device is identical to the primary predicate device and within the range of the secondary predicate device
ON Time (seconds)	Gait Mode: Maximum 5 seconds after triggering event Exercise Mode: Maximum 20 seconds after triggering event. Interleaved Afferent Stimulation: Pulse bursts are triggered at the start of gait mode or exercise mode and terminated at the end of the mode. Stimulation pulses of the afferent pulse train are interleaved with pulses from the FES pulse trains of gait and exercise mode.	not publicly available	1-20 sec	The subject device and the secondary predicate device have equivalent stimulation ON times in Exercise Mode (up 20 seconds). When compared to the secondary predicate device, the subject device includes an additional feature—Interleaved Afferent Stimulation—where low-frequency pulse bursts are triggered at the start of each mode and terminate at the end of the mode. These afferent pulses are interleaved with the standard FES pulses and do not extend the total duration of stimulation. This implementation does not increase total stimulation time or intensity and remains within known safe and effective use parameters for neuromuscular stimulation. Therefore, this difference does not raise any issues related to safety or effectiveness since all three devices adhere to recognized/consensus electrical safety standards and are similar within the range
OFF Time (seconds)	Exercise Mode: maximum 60 seconds Gait Mode: not limited	not publicly available	1-30 sec	The subject device is similar to the secondary predicate device. Differences have no impact on safety and effectiveness since all three devices adhere to recognized/consensus electrical safety standards and are similar within the range

Note: The FES functionality within the NS-200 and NS-100 can be subdivided into two broad categories:

1. **Gait Mode**: Here, sEMG is used **solely for monitoring** the user's muscle activities but does not drive or trigger stimulation.

2. **Exercise Mode**: In these protocols, sEMG **has a closed-loop control** role, where the user's muscle activation signals can directly impact stimulation timing and intensity. This approach synchronizes stimulation delivery with voluntary muscle activation to enhance neuromuscular reeducation and functional performance.

Table 3. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Powered Muscle Stimulator

Characteristic	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE	SE Comparison
510(k) Number	K243828	K221823	K080950	
Device Name, Model	NS-200	NS-100	STIWELL med4	
Manufacturer	Cionic Inc.	Cionic Inc.	Otto Bock Healthcare Product GmbH	
Regulation	21 CFR 882.5810	21 CFR 882.5810	21 CFR 890.5850	
Product codes	GZI, IPF, HCC	GZI, IPF	IPF, GZJ, HCC, GZI, KPI	
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Battery Pack Li-Ion 11.1V	The subject device's battery is identical to the battery of the primary predicate device and is very similar to the battery of the secondary predicate device. 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 on safety and effectiveness since all three devices adhere to recognized/consensus electrical/battery safety standards.
Method of Line Current Isolation	Medical Class II Power Adapter Input: 100-240V 50/60Hz Output: 5V 2A using SB-C cable	not publicly available	Medical Class II Power Adapter – Mascot (12.6VDC-15.1W)	Differences when compared to the secondary predicate device are considered minor with no impact on safety and effectiveness
Number of Output Modes	1 mode: Monophasic with hybrid stimulation	1 mode: Monophasic with hybrid stimulation	1	The subject device is identical to the primary predicate device. Differences when compared to the secondary predicate device are considered minor

				with no impact on safety and effectiveness
Number of Output Channels	1 stimulator channel with 8 virtual Positive and 15 virtual Negative output channels	1 stimulator channel with 8 virtual Positive and 15 virtual Negative output channels	4	The subject device is identical to the primary predicate device. Compared to the secondary predicate device, the subject device includes fewer physical stimulation channels. However, it achieves the same therapeutic effects and delivers equivalent stimulation parameters by incorporating a 24-channel high-voltage multiplexer (MUX). This MUX functions as an electronic switch that time-shares a single stimulation output across multiple electrodes in rapid succession. Differences are considered minor with no impact on safety and effectiveness.
Synchronous or Alternating	Alternating	Not publicly available	Alternating	Identical to the secondary predicate device
Method of Channel Isolation	The virtual output channels are multiplexed through a 24-channel high voltage analog switch with channel isolation of -33 dB (typical), Switch crosstalk of -70 dB (typical) and switch-off leakage current of 1 µA typical per switch	Not publicly available	Transformer, Inductive couplers	Both the subject and the secondary predicate devices are using high voltage FET switches. The secondary predicate device uses a different method of isolation, but both methods achieve the same result. This was based on the results of the channel isolation bench test, and the IC manufacturer datasheet.
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Regulated Current	Identical to both predicate devices
Software/Firmware Microprocessor Control?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Automatic Overload Trip, No-Load Trip, Shut Off?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Patient Override Control?	Yes (Stop Button)	Not publicly available	Yes (Stop Button)	Identical to the secondary predicate device
Indicator Display On/Off Status?	Yes	Not publicly available	Yes	Identical to the secondary predicate device

Indicator Display: Low Batt?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Indicator Display: Voltage Current Level?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Timer Range (minutes)	Exercises 1-60 minutes	Not publicly available	2-120 min	Differences between the subject and the secondary predicate devices in timer range are considered minor since overall intended uses are the same and ultimately achieve the same result i.e., muscle stimulation
Compliance with voluntary Standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Not publicly available	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Identical to the secondary predicate device
Compliance with 21 CFR 898	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Weight	Control Unit (DC-200) 145g Sleeve (SL-200 Left and Right) X-Small (S0) 220g Small (S2) 230g Medium (S4) 240g Large (S6) 250g	DC-100 145 g SL-100 Medium 240g SL-100 Small 230g	440 g	The subject device is identical to the primary predicate device in the weight of the Control Unit, Medium Sleeve, and Small Sleeve. The subject device's sleeve has more options in size (i.e., X-small and Large). This difference is insignificant and does not raise any issues of safety and effectiveness. Although the appearance, weight, and dimensions are different between the subject and secondary predicate devices, these differences are insignificant and do not raise any issues related to safety and effectiveness
Dimensions [W x H x D]	Control Unit (DC-200) 136 x 54 x 24 mm Sleeve (SL-200 Left and Right) X-Small (S0) 500 x 600 mm Small (S2) 520 x 610 mm Medium (S4) 580 x 630 mm Large (S6) 690 x 680 mm	DC-100 137 x 53 x 24 mm SL-100 Medium 613 x 602 mm SL-100 Small 596 x 560 mm	Device: 175 x 95 x 30 mm	The subject device's dimension is very similar when compared to the primary predicate device. This difference in dimension is insignificant and does not raise any issues of safety and effectiveness. Although the appearance, weight, and dimensions are different between the subject and secondary predicate devices, these differences are insignificant and do not raise any issues

				related to safety and effectiveness
Waveform (e.g., pulsed monophasic, biphasic)	Monophasic with hybrid stimulation	Not publicly available	Biphasic Symmetrical	Although the stimulation waveform of the subject device is different from that of the secondary predicate, the subject device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness
Shape	Rectangular	Not publicly available	Rectangular	Identical to the secondary predicate device
Maximum Output Voltage (+/- 10%) [V]	50V @ 500 Ω 125V @ 2 kΩ 130V @ 10 kΩ	Not publicly available	50V @ 500 Ω 115V @ 2 kΩ N/A @ 10 kΩ	Differences between the subject and the secondary predicate devices are considered minor and have no impact on safety and effectiveness since they adhere to recognized consensus and standards and the values are similar within range
Maximum Output Current (+/- 10%) [mA]	100 mA @ 500 Ω 62.5 mA @ 2 kΩ 13 mA @ 10 kΩ Irms=24.6 mA computed based on 500 Ω 100mA (+/- 10%) 400 µs 125 Hz	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	100 mA @ 500 Ω 58 mA @ 2 kΩ N/A @ 10 kΩ Irms N/A	The subject device is very similar to the predicate devices. Differences are considered minor and have no impact on safety and effectiveness since all three devices adhere to recognized consensus and standards and the values are similar within range
Pulse width	100, 200, 300, and 400µs Default 300µs	Not publicly available	50 to 400 µs	Very similar when compared to the secondary predicate. Although the pulse width ranges are different from that of the secondary predicate, the proposed device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness.
Frequency [Hz]	5 – 125 Hz in 5Hz increment Default 35Hz	Not publicly available	1 – 140 Hz	Very similar when compared to the secondary predicate. Although the frequency ranges are different from that of the secondary predicate, the proposed device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness.

Net Charge [µC/pulse] (500Ω)	0 µC using Hybrid Stimulation	Not publicly available	0 µC Same positive and negative impulse	The subject device is very similar when compared to the secondary predicate. Although the method used to achieve 0 µC is different from that of the secondary predicate, the proposed device has passed IEC 60601-1 and IEC 60601-2-10, so this difference should not affect safety and effectiveness
Maximum Phase Charge[µC] @ 500Ω	40 [µC] @ 500Ω 400 µs * 100 mA = 40 µC	Not publicly available	40 [µC] @ 500Ω	Identical to the secondary predicate device
Maximum Current (RMS) Density [mA/cm^2]	1.24 mA/cm^2] Irms=24.6 mA computed based on 500 Ω 100mA (+/- 10%) 400 µs 125 Hz electrode area of 19.8cm^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	12.5 mA/cm^2	The Maximum Current Density of the subject device is very similar when compared to that of the primary predicate device. Differences are considered minor and have no impact on safety and effectiveness since all three devices adhere to recognized consensus
Maximum Power Density [mW/cm^2]	12mW/cm^2 (500 Ω, Irms=24.6 mA, electrode area of 19.8 cm^2)	12mW/cm^2 (500 Ω, Irms=24.6 mA, electrode area of 25 cm^2)	7.9mW/cm2	The subject device is identical to the primary predicate device and within the range of the secondary predicate device
ON Time (seconds)	Exercise Mode: Maximum 20 seconds after triggering event. Interleaved Afferent Stimulation: Pulse bursts are triggered at the start of exercise mode and terminated at the end of the mode. Stimulation pulses of the afferent pulse train are interleaved with pulses from the stimulation pulse trains of exercise mode.	Not publicly available	1-20 sec	The subject device and the secondary predicate device have equivalent stimulation ON times Exercise Mode. The subject device includes an additional feature—Interleaved Afferent Stimulation—where low-frequency pulse bursts are triggered at the start of each mode and terminate at the end of the mode. These afferent pulses are interleaved with the standard FES pulses and do not extend the total duration of stimulation. This implementation does not increase total stimulation time or intensity and remains within known safe and effective use parameters for neuromuscular stimulation. Therefore, this difference does not raise any issues related to safety or effectiveness.

OFF Time (seconds)	Exercise Mode: maximum 60 seconds	Not publicly available	1-50 sec	The subject device is very similar to the secondary predicate device. Differences are considered minor and have no impact on safety and effectiveness since they all adhere to recognized/consensus electrical safety standards and are similar within the range
Note: For the NS-200 and NS-100 devices, the sEMG functionality is not active in Powered Muscle Stimulator mode				

Table 4. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Biofeedback

Characteristic	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE	SE Comparison
510(k) Number	K243828	K221823	K080950	
Device Name, Model	NS-200	NS-100	STIWELL med4	
Manufacturer	Cionic Inc.	Cionic Inc.	Otto Bock Healthcare Product GmbH	
Regulation	21 CFR 882.5810	21 CFR 882.5810	21 CFR 890.5850	
Product codes	GZI, IPF, HCC	GZI, IPF	IPF, GZJ, HCC, GZI, KPI	
Power Source(s)	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Lithium Polymer (LiPo) rechargeable 7.4V 1900mAh	Battery Pack Li-Ion 11.1V	The subject device's battery is identical to the battery of the primary predicate device and is very similar to the battery of the secondary predicate device. 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 on safety and effectiveness since all three devices adhere to recognized/consensus electrical/battery safety standards.

Method of Line Current Isolation	Medical Class II Power Adapter Input: 100-240V 50/60Hz Output: 5V 2A using USB-C cable	not publicly available	Medical Class II Power Adapter – Mascot (12.6VDC-15.1W)	Differences when compared to the secondary predicate device are considered minor with no impact on safety and effectiveness since all three devices adhere to recognized/consensus electrical safety standards and all devices are similar within range
Number of Output Modes	1 mode: Monophasic with hybrid stimulation	1 mode: Monophasic with hybrid stimulation	1	The subject device is identical to the primary predicate device. Differences when compared to the secondary predicate device are considered minor with no impact on safety and effectiveness
Number of Output Channels	1 stimulator channel with 8 virtual Positive and 15 virtual Negative output channels	1 stimulator channel with 8 virtual Positive and 15 virtual Negative output channels	1	The subject device is identical to the primary predicate device. Compared to the secondary predicate device, the subject device includes fewer physical stimulation channels. However, it achieves the same therapeutic effects and delivers equivalent stimulation parameters by incorporating a 24-channel high-voltage multiplexer (MUX). This MUX functions as an electronic switch that time-shares a single stimulation output across multiple electrodes in rapid succession. Differences are considered minor with no impact on safety and effectiveness.
Number of EMG (input) Channels	8	Not publicly available	2	When compared to the secondary predicate device, differences are considered minor (therefore no impact on safety and effectiveness) since the subject and the predicate devices measure muscle activity via EMG by detecting the electrical signal during activity
EMG Sensitivity	0.0298 µV	Not publicly available	1 µV	When compared to the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity

EMG Sampling Rate	2kHz	Not publicly available	3kHz	When compared to the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.
EMG detection (bipolar/monopolar)	Bipolar	Bipolar	Bipolar	Identical to both predicate devices
EMG range (μV)	$+/-2.5*10^6$ μV	Not publicly available	1-2000 μV	When compared to the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.
EMG bandwidth	10-500 Hz	Not publicly available	70-480 Hz	When compared to the secondary predicate device, differences are considered minor since both devices measure muscle activity by detecting the electrical signal during activity.
EMG signal processing (e.g. RMS)	RMS (Root Mean Square)	Not publicly available	AVR (Average Rectified Value)	When compared to the secondary predicate device, differences in EMG signal processing does not lead to questions of safety and effectiveness because both RMS and AVR can be used to quantify the amplitude or magnitude of the EMG signal, providing an estimate of muscle activity
Synchronous or Alternating	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Method of Channel Isolation	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Regulated Current or Regulated Voltage	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Software/Firmware Microprocessor Control?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Automatic Overload Trip, No-Load Trip, Shut Off?	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Patient Override Control?	Yes (Stop Button)	Not publicly available	Yes (Stop Button)	Identical to the secondary predicate device

Indicator Display On/Off Status?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Indicator Display: Low Batt?	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Indicator Display: Voltage Current Level?	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Timer Range (minutes)	Exercises 1-60 minutes	Not publicly available	5-30 min	When compared to the secondary predicate device, differences in timer range are considered minor since overall intended uses are the same and ultimately achieve the same result i.e., muscle stimulation
Compliance with voluntary Standards?	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Not publicly available	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10	Identical to the secondary predicate device
Compliance with 21 CFR 898	Yes	Not publicly available	Yes	Identical to the secondary predicate device
Weight	Control Unit (DC-200) 145g Sleeve (SL-200 Left and Right) X-Small (S0) 220g Small (S2) 230g Medium (S4) 240g Large (S6) 250g	DC-100 145 g SL-100 Medium 240g SL-100 Small 230g	440 g	The subject device is identical to the primary predicate device in the weight of the Control Unit, Medium Sleeve, and Small Sleeve. The subject device's sleeve is available in X-small and Large. This difference is insignificant and does not raise any issues of safety and effectiveness. Although the appearance, weight, and dimensions are different between the subject and secondary predicate devices, these differences are insignificant and do not raise any issues related to safety and effectiveness
Dimensions [W x H x D]	Control Unit (DC-200) 136 x 54 x 24 mm Sleeve (SL-200 Left and Right) X-Small (S0) 500 x 600 mm Small (S2) 520 x 610 mm Medium (S4) 580 x 630 mm Large (S6) 690 x	DC-100 137 x 53 x 24 mm SL-100 Medium 613 x 602 mm SL-100 Small 596 x 560 mm	Device: 175 x 95 x 30 mm	The subject device's dimension is very similar when compared to the primary predicate device. This difference in dimension is insignificant and does not raise any issues of safety and effectiveness. Although the appearance, weight, and dimensions are different between the subject and secondary predicate devices, these differences

	680 mm			are insignificant and do not raise any issues related to safety and effectiveness
Waveform (e.g., pulsed monophasic, biphasic)	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Shape	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Maximum Output Voltage (+/- 10%) [V]	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Maximum Output Current (+/- 10%) [mA]	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Pulse width	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Frequency [Hz]	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Net Charge [µC/pulse] (500Ω)	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Maximum Phase Charge[µC] @ 500Ω	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Maximum Current (RMS) Density [mA/cm^2]	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Maximum Power Density [mW/cm^2]	N/A	Not publicly available	N/A	Identical to the secondary predicate device
ON Time (seconds)	N/A	Not publicly available	N/A	Identical to the secondary predicate device
OFF Time (seconds)	N/A	Not publicly available	N/A	Identical to the secondary predicate device
Stimulation Threshold	20% of the maximum activation level recorded during EMG Calibration	Not publicly available	Not publicly available	Although the threshold values for the predicate devices are not publicly available, the subject device's method is consistent with standard clinical practices and accepted safety margins in neuromuscular stimulation. As such, this difference does not raise concerns regarding safety or effectiveness.

VIII PERFORMANCE DATA

Summary of Nonclinical Performance Testing

The tests listed have been conducted to demonstrate that the Cionic Neural Sleeve NS-200 performs as intended and is substantially equivalent to both predicate devices.

- Stimulation Output Waveforms
- 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
- Software validation according to IEC 62304

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

  - Usability according to IEC 62366; IEC 60601-1-6 (Summative Evaluation)

Summary of Literature Clinical Data

- The Cionic Neural Sleeve NS-200 stimulates dorsiflexors and evertors of the leg to provide foot eversion. There is no new intended use when compared to the intended use of the primary predicate device, NS-100 (K221823). The new indication of providing foot eversion is supported by the article titled "Augmenting Gait in a Population Exhibiting Foot Drop with Adaptive Functional Electrical Stimulation" (https://www.medrxiv.org/content/10.1101/2022.04.27.22273623v2.full).

IX CONCLUSION

The Cionic Neural Sleeve NS-200 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 both predicate devices.