May 11, 2021

Ibramed Equipamentos Medicos
% Rodrigo Abreu
Regulatory Specialist
United Regulatory LLC
12343 NW 25th St
Coral Springs, Florida 33065

Re: K210572
Trade/Device Name: Neurodyn V2.0, Neurodyn Aussie V2.0
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: February 26, 2021
Received: February 26, 2021

Dear Rodrigo Abreu:

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,

Patrick Antkowiak, PhD
Assistant Director (Acting)
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210572

Device Name
Neurodyn V2.0, Neurodyn Aussie V2.0

Indications for Use *(Describe)*
Neurodyn V2.0 Stimulators are intended for:
As a FES device:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

As a TENS device:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical pain

As an Interferential and Premodulated device:
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:
- Temporary relaxation of muscle spasms - Prevention or retardation of disuse atrophy in post-injury type conditions - Increase local blood circulation - Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:
- Symptomatic relief of chronic intractable pain - Symptomatic relief of post-traumatic acute pain and post surgical pain

As a DC/Polarized device:
-Relaxation of Muscle Spasm

As a High Voltage Pulsed current device:
- Muscle re-education
- Relaxation of Muscle Spasms
- Maintaining or increasing range of motion
- Increasing local blood circulation
- Prevention or retardation of disuse atrophy

Neurodyn Aussie V2.0 Stimulators are intended for:
As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation

- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

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

May 10, 2021

A) Submitter's Name: Ibramed Equipamentos Médicos

Owner / Operator Registration Number: 3010362721

Manufacture Registration Number: 3010362721

B) Address: Av. Dr. Carlos Burgos, 2800 - Jardim Itália, Amparo - SP, 13901-080 Brazil

C) Phone and Fax Numbers

Phone: + 55 19 3817 9633

D) Contact Person:

Fábio Alexandre Pinto

Tel.: +55 19 3817-9636

E) Preparation Date: May 10, 2021

F) Classification Name: Powered Muscle Stimulator

Common / Usual Name: Powered Muscle Stimulator

Proprietary Name: Neurodyn V2.0; Neurodyn Aussie V2.0

Product Code: IPF

Class: Class II

Regulation: 21 CFR 890.5850

G) Device Description

NEURODYN v2.0 is a transcutaneous neuromuscular stimulator of four channels with independent controls for treatments with: AUSSIE CURRENT (with Medium Frequency Current modulated in Burst), RUSSIAN CURRENT (Medium Frequency Current modulated in Burst), FES CURRENT (Functional Electrical Stimulation),TENS CURRENT(Transcutaneous Electrical Nerve Stimulation), INTERFERENTIAL CURRENT (IFC-T), PREMODULATED INTERFERENTIAL CURRENT (IFC-B) BIPOLAR (Medium Frequency Current modulated in Amplitude), and with two independent control channels for the treatments with: MICROCURRENT (Microcurrent Electrical Neuromuscular Stimulation), DIRECT CURRENT /POLARIZED CURRENT and HIGH VOLTAGE PULSED CURRENT (High Volt Pulsed Current).

NEURODYN AUSSIE V2.0 transcutaneous neuromuscular stimulator is a four-channel stimulator with independent controls for current therapy used in AUSSIE CURRENT (Burst Modulated Medium Frequency).

H) Substantial Equivalence:

The Neurodyn V2.0 is equivalent with the following products:

Predicate type	510(k) Number	Model	Company
Predicate	K131629	Neurodyn Multiwave; Neurodyn Aussie Sport	Ibramed Equipamentos Médicos
Secondary Predicate	K031077	Vectra Genesis	Chattanooga

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I) Indications for Use:

1. Subject device: Neurodyn V2.0, Neurodyn Aussie V2.0

Neurodyn V2.0 Stimulators are intended for:
As a FES device:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

As a TENS device:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical pain

As an Interferential and Premodulated device:
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:
- Temporary relaxation of muscle spasms - Prevention or retardation of disuse atrophy in post-injury type conditions - Increase local blood circulation - Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:
- Symptomatic relief of chronic intractable pain - Symptomatic relief of post-traumatic acute pain and post surgical pain

As a DC/Polarized device:
-Relaxation of Muscle Spasm

As a High Voltage Pulsed current device:
- Muscle re-education
- Relaxation of Muscle Spasms
- Maintaining or increasing range of motion
- Increasing local blood circulation
- Prevention or retardation of disuse atrophy

Neurodyn Aussie V2.0 Stimulators are intended for:
As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions

- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

2. **Predicate: Neurodyn Multiwave; Neurodyn Aussie Sport**

Neurodyn Multiwave-Indications for Use:
As a FES device:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

As a TENS device:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

As an Interferential and Premodulated device:
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:
- Temporary relaxation of muscle spasms - Prevention or retardation of disuse atrophy in post-injury type conditions - Increase local blood circulation - Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:
- Symptomatic relief of chronic intractable pain - Symptomatic relief of post-traumatic acute pain and post surgical pain

As a DC/Polarized device:
-Relaxation of Muscle Spasm

Aussie Sport- Indications for Use:

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

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- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

3. Secondary Predicate Device: Vectra Genesis

Indications for Use for High Voltage current device:
- Muscle re-education
- Relaxation of Muscle Spasms
- Maintaining or increasing range of motion
- Increasing local blood circulation
- Prevention or retardation of disuse atrophy

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K) Technological Characteristics Comparison:

The predicate device used to establish substantial equivalence for the **Neurodyn V2.0, Neurodyn Aussie V2.0** device is outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Neurodyn V2.0 to each of the predicate devices stratified by functional modality.

Device name	**Neurodyn_V2.0; Neurodyn Aussie_V2.0**	**Neurodyn Multiwave; Neurodyn Aussie Sport**	**Vectra Genesis**	**SE Discussion of the differences**
K Number	K210572	K131629	K031077	N/A
Manufacturer	Ibramed	Ibramed	Chattanooga	N/A
Population target	Patients must be at least 12 years of age and Patients must weigh at least 35 kg.	Patients must be at least 12 years of age and Patients must weigh at least 35 kg.	Not stated in the Manual	Identical when compared with Neurodyn
Environment	Hospitals, Clinics, o medical environment	Hospitals, Clinics, o medical environment	Hospitals, Clinics, o medical environment	Identical
Technological characteristics Medium-frequency alternating current (MFAC)	Identical	Identical	Similar	N/A
Housing Material	ABS plastic panel LCD display	ABS plastic panel LCD display	Not stated in the Manual	N/A
Dimensions W x H x D (in)	Neurodyn V2.0 14.6 x 4.9 x 12.4 Aussie: 10.6 x 4.9 x 10.4	6.8 x 4.9 x 12.4	11.38 x 8.75 x 12.75	N/A
Weight	5Lb	5Lb	7Lb	N/A
Number of Channels	Up to 4	Up to 4	Up to 4	Identical
Temperature range during transport and storage	41°F-122°F	41°F-122°F	59° F and 104° F	The ranges are very similar not affecting the substantial equivalence.

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Environment operating temperature range	41°f-113°f	41°F-113°F	No specified	The ranges are very similar not affecting the substantial equivalence.
Performance	Identical	Identical	Identical	Identical
Biocompatibility	FDA cleared electrodes	FDA cleared electrodes	FDA cleared electrode	Identical
Mechanical safety	Identical	Identical	Identical	Identical
Anatomical Sites	Identical	Identical	Similar	N/A
Burst Modulated Alternating Current (Russian)	Yes	Yes	Yes	Identical
Burst Modulated Alternating Current (Aussie)	Yes	Yes	No	Vectra does not have the Aussie current but the Neurodyn contains, supporting the substantial equivalence.
Interferential	Yes	Yes	Yes	Identical
Microcurrent	Yes	Yes	Yes	Identical
TENS	Yes	Yes	Yes	Identical
FES	NEURODYN_V2.0: Yes NEURODYN AUSSIE_V2.0: No	Yes	No	Vectra does not have the FES current but the Neurodyn contains, supporting the substantial equivalence.
Premodulated	Yes	Yes	Yes	Identical
High Volt	Yes	No	Yes	Neurodyn does not have the HV current but the Vectra contains,

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				supporting the substantial equivalence.
Method of current isolation	Double Isolation	Double Isolation	Double Isolation	Identical
Patient leakage control-normal condition	NEURODYN_V2.0: 0.0044 mA NEURODYN AUSSIE_V2.0: 0.0134 mA	0.0508mA	100µA	It is between the standard acceptance range, supporting the substantial equivalence.
Patient leakage control-single fault condition	NEURODYN_V2.0: 0.0124 mA NEURODYN AUSSIE_V2.0: 0.0008 mA	0.0252mA	500µA	It is between the standard acceptance range, supporting the substantial equivalence.
Number of output mode	NEURODYN_V2.0: 8 NEURODYN AUSSIE_V2.0: 1	7	10	Number of modalities that the equipment provides, the modalities are independent and do not need each other to carry out the treatment, limiting only the number of treatments performed according to the supplied currents.
Synchronous or Alternating?	Synchronous	Synchronous	Synchronous	Identical
Method of Channel isolation	Output transformation with isolation to 1000V	Output transformation with isolation to 1000V	Not Stated in the Manual	Identical when compared with Neurodyn
Regulated current or regulated voltage?	Only Current	Only Current	Optional	Circuit regulated in current or voltage does

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			Current or Voltage	not interfere in performance, but circuit regulated in current is more common.
Software Microprocessor	Yes	Yes	Yes	Identical
Automatic overload trip	No	No	Not Stated in the Manual	Identical when compared with Neurodyn
Automatic no-load trip	No	No	Not Stated in the Manual	Identical when compared with Neurodyn
Automatic shut off	Yes	Yes	Yes	Identical
Patient override control?	Yes	Yes	Yes	Identical
Indicator Display On/off Status?	Yes	Yes	Yes	Identical
Indicator Display Voltage/Current Level?	NEURODYN_V2.0: Aussie 0 to 120mA (Ipp) NEURODYN AUSSIE_V2.0: Aussie 0 to 120mA (Ipp)	Aussie 0 to 120mA (Ipp)	No	Identical when compared with Neurodyn
	NEURODYN_V2.0: Russa 0 to 120mA (Ipp)	Russa 0 to 120mA (Ipp)	Russian 0 to 100 mA	Characteristics of the circuit, does not interfere in the performance, since the intensity does not have fixed parameter, it is according to the sensorial of each patient.
	NEURODYN_V2.0: TENS 0 to 120mA (Ipp)	TENS 0 to 120mA (Ipp)	Tens 0 to 80 mA	Characteristics of the circuit, does not interfere in the performance, since the intensity does not

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				have fixed parameter, it is according to the sensorial of each patient.
	NEURODYN_V2.0: FES 0 to 120mA (Ipp)	FES 0 to 120mA (Ipp)	No	Identical when compared with Neurodyn
	NEURODYN_V2.0: Interferential TP 0 to 120mA (Ipp)	Interferential TP 0 to 120mA (Ipp)	Interferential 0 to 100 mA	Characteristics of the circuit, does not interfere in the performance, since the intensity does not have fixed parameter, it is according to the sensorial of each patient.
	NEURODYN_V2.0: Interferential BP 0 to 120mA (Ipp)	Interferential BP 0 to 120mA (Ipp)	Interferential 0 to 100 mA	Characteristics of the circuit, does not interfere in the performance, since the intensity does not have fixed parameter, it is according to the sensorial of each patient.
	NEURODYN_V2.0: Micro Current 0 to 990µA (Ip)	Micro Current 0 to 990µA (Ip)	Micro Current 0 to 100 µA	Characteristics of the circuit, does not interfere in the performance, since the intensity does not have fixed parameter, it is according to the sensorial of each patient.
	NEURODYN_V2.0: Polarized/ Direct Current 0 to 30 mA (Ip)	Polarized/ Direct Current 0 to 30 mA (Ip)	Direct Current 0 to 4 mA	Characteristics of the circuit, does not interfere in the performance, since the intensity does not have fixed parameter, it

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				is according to the sensorial of each patient.
	High Volt 0 to 400 V		High Volt 0 to 500V	Characteristics of the circuit, does not interfere in the performance, since the intensity does not have fixed parameter, it is according to the sensorial of each patient.
Locking feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature	Identical
Treatment timer	Treatment timer with auto shut off 1-60 minutes	Treatment timer with auto shut off 1-60 minutes	Treatment timer with auto shut off 1-60 minutes	Identical
Voltage Input Range and Frequency	100-240VAC, 50/60Hz	100-240VAC, 50/60Hz	100-240VAC, 50/60Hz	Identical
Safety standards requirements biocompatibility	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 21 CFR 898	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 21 CFR 898	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 21 CFR 898	Identical

Conclusion: The Neurodyn V2.0 device and the predicate devices are substantially equivalent when comparing the indications for use, and technological properties. The differences shown in the comparison do not affect the substantial equivalence.

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L) Applicable Standards:

Neurodyn V2.0 was developed, as well produced in compliance with recognized international regulations and standards for the medical device industry.

IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-2-10 - Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

Conclusion:

Based on compliance with the international standard and regulation mentioned above, the device Neurodyn V2.0 demonstrate substantial equivalence to the predicates above.

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M) Non-clinical Testing:

In order to study the performance of the product, pre-clinical tests were performed according to the table below.

Test Performance
IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance **IEC 60601-2-10** - Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Conclusion: Based on compliance with the international standard and regulation mentioned above, the device Neurodyn V2.0 demonstrates equivalency to the predicate device.