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JUL 0 3 2014

510(k) Summary

510 (k) Number: K131923
Date of Submission: July 1, 2014

Submitter:
IBRAMED EQUIPAMENTOS MEDICOS
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Common Name:	External Functional Neuromusclar Stimulator
Trade Name:	Neurodyn Portable TENS; Neurodyn Portable TENS/FES
Classification:	Class II
Product Code:	GZJ; GZI
Classification Panel:	Neurology
Regulation Numbers:	21 CFR 882.5890 and 21 CFR 882.5810
Substantial Equivalence:	K121369 Neurodyn/Aussie Powered Muscle Stimulator by Ibramed; K021100 300 PV Complete Electrotherapy System by EMPI

Indications for Use

Indications for 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.

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

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Device Description

Neurodyn Poratble TENS/FES

The device NEURODYN PORTABLE TENS/FES is a two output channel stimulator, operated in power supply 100 to 240 V 50-60 Hz AC/9V DC converter, with independent controls, Liquid Crystal Display with 4 ½ digits, mechanical contact keyboard and ABS cabinet.

Used in the following electrical current therapies:
TENS (Transcutaneous Electrical Nerve Stimulation)
FES (Functional Electrical Stimulation)

The equipment must be used only under the prescription and supervision of a licensed health professional.

Neurodyn Portable Tens/Fes

Characteristics:

- TENS: two 100mA peak to peak channels
- FES: two 100mA peak to peak channels
- Input Power: 15VA
- Temperature Range During Transport and Storage: 41 to 122°F
- Environment Operating Temperature Range: 41 to 113°F
- Electrical Class: Class II
- Electrical Protection: Type BF

Neurodyn Portable TENS

The device NEURODYN PORTABLE TENS is a two output channel stimulator, operated in power supply 100 to 240 V 50-60 Hz AC/9V DC, with independent controls, Liquid Crystal Display with 4 ½ digits, mechanical contact keyboard and ABS cabinet.

Used in the following electrical current therapies:
TENS (Transcutaneous Electrical Nerve Stimulation)

The equipment must be used only under the prescription and supervision of a licensed health professional.

Neurodyn Portable Tens

Characteristics:

- TENS: two 100mA peak to peak channels
- Input Power: 15VA
- Temperature Range During Transport and Storage: 41 to 122°F
- Environment Operating Temperature Range: 41 to 113°F
- Electrical Class: Class II

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Electrical Protection: Type BF

Device Comparison Table

Device name	Neurodyn Portable TENS/FES	Neurodyn Portable TENS	Neurodyn	300 PV Empi
K Number	K131923	K131923	K121369	K021100
Manufacturer	Ibramed	Ibramed	Ibramed	Empi
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 FES device: Stimulation of 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 NMES device: Retarding or preventing disuse atrophy Maintaining or increasing range of motion Reeducating muscles Relaxation of muscle spasm Increasing local blood circulation Prevention of venous thrombosis of the calf muscles immediately after surgery
	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	As a TENS device: Symptomatic relief of chronic (long term) intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	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 pain, acute post traumatic pain, or acute post traumatic surgical pain	As an Interferential This device is not been used as a predicate for the Interferential waveform

			As a Burst Modulated Alternating Current -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	
			As a Microcurrent device: Symptomatic relief of chronic intractable pain Symptomatic relief of post-traumatic acute pain and post surgical pain	
Technological characteristics Medium-frequency alternating current (MFAC)	Identical	Identical	Identical	Identical
Device Material	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display	ABS plastic panel LCD display
Width (in)	3.07	3.07	6.8	9.75
Height	1.97	1.97	4.9	8.75

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Depth	5.83	5.83	12.4	12.75
Number of Channels	2	2	4	4
Temperature range during transport and storage	-58°f-122°f	-58°f-122°f	45°f-110°f	-40 to 158°F
Environment operating temperature range	23°F-113°F	23°F-113°F	45°F-110°F	50 to 104°F
Method of current isolation	Double Isolation	Double Isolation	Double Isolation	Double Isolation
Patient leakage control-normal condition	0.0497 mA	0.0497 mA	0.0508mA	0.0502mA
Patient leakage control-single fault condition	0.0245 mA	0.0245 mA	0.0252mA	0.0248mA
Software Microprocessor	Yes	Yes	Yes	Yes
Automatic overload trip	No	No	No	No
Automatic shut off	No	No	No	No
Locking feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature	Keyboard lock safety feature
Treatment timer	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer with auto shut off	Treatment timer
Safety standards requirements biocompatibility	IEC 60601-1 IEC 60601-2 IEC 60602-10	IEC 60601-1 IEC 60601-2 IEC 60602-10	IEC 60601-1 IEC 60601-2 IEC 60602-10	IEC 60601-1 IEC 60601-2 IEC 60602-10
Chemical Composition	Has no Chemical Composition	Has no Chemical Composition	Has no Chemical Composition	Has no Chemical Composition
Energy Source	AC/9.0 DC	AC/9.0 DC	9.0 DC	3.0 DC
Electrical Output Parameters	TENS 0 to 100mA peak to peak FES 0 to 100mA peak to peak	TENS 0 to 100mA peak to peak	FES 0 to 120mA peak to peak RUSSIA 0 to 120mA peak to peak Interferential 0 to 120mA peak to peak Aussie 0 to 120mA peak to peak Micro current 0 to 990µA peak	NMES 0 to 100mA peak to peak TENS 0 to 50mA peak to peak HV 0 to 300V peak
Modes of stimulation	TENS FES	TENS	TENS FES INTERFERENTIAL RUSSA AUSSIE DIRECT CURRENT MICRO CURRENT	TENS NMES INTERFERENTIAL HV
Frequency Hz	0.5 to 250	0.5 to 250	0.5 to 250	0.5 to 150
Phase Duration µs	50 to 500	50 to 500	50 to 500	50 to 400
Current Output mA	104	104	125	200
Total Charge per pulse (two phases)	52	52	57	40
Maximum Average Power Density	0.024	0.027	0.040	0.0088

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W/cm²				

Substantial Equivalence

The subject and the predicate devices have the same intended use, the same operating principle, and are similar in their hardware configuration.

Technology

The Neurodyn Portable devices are External Functional Neuromusclar Stimulator machines that operate using the tens and/or fes waveforms.

Conclusion

The Neurodyn Portable TENS and Neurodyn Portable TENS/FES machines are substantially equivalent to the currently legally marketed Neurodyn and 300 PV. The non-clinical testing demonstrates that the subject devices are as safe, as effective and perform as well or better than the legally marketed predicated devices. The IEC testing showed that the subject devices comply with Medical Electrical Device requirements for external functional neuromusclar stimulator. The subject devices passed all aspects of the clinical tests. This shows compliance with the standards currently in place for such medical devices. Compliance includes but is not limited to electrical safety (power input, electrical classification, limitation of voltage/energy, etc.).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 3, 2014

Ibramed Equipamentos Medicos
C/O TechLink International Consulting
Attn: Tara Conrad
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

Re: K131923

Trade Name: Neurodyn Portable TENS/FES and Neurodyn Portable TENS
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI, GZJ
Dated: June 23, 2014
Received: June 25, 2014

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131923

Device Name: Neurodyn Portable TENS and Neurodyn Portable TENS/FES

Indications For Use:

Indications for 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.

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

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Felipe Aguel -S Date: 2014.07.03 17:01:44 -04'00'