August 13, 2020

Pierenkemper GmbH
% Andre Kindsvater
Senior Consultant RA & QA
Emergo Global Consulting
2500 Bee Cave Rd, Building 1, Suite 300
Austin, Texas 78746

Re: K181645
Trade/Device Name: StimaWELL 120MTRS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: May 10, 2020
Received: May 15, 2020

Dear Andre Kindsvater:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber Ballard, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181645

Device Name
StimaWELL®120MTRS

Indications for Use *(Describe)*
TENS mode:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-tramautic acute pain and post surgical pain

Russian mode:
- Temporary relaxation of muscle spasms in back area
- Prevention or retardation of disuse atrophy of the lumbar paraspinal muscles

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

StimaWELL 120MTRS

K181645

1. Submission Sponsor

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3. Date Prepared

August 6th, 2020

4. Device Identification

Trade/Proprietary Name:	StimaWELL 120MTRS
Common/Usual Name:	Nerve and Muscle stimulator for pain relief
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief Powered muscle stimulator
Regulation Number	882.5890 890.5850
Product Codes	GZJ IPF
Regulation Name	Stimulator, Nerve, Transcutaneous, For Pain Relief Stimulator, Muscle,Powered

5. Legally Marketed Predicate Devices

a) Electro-therapy (primary)
K131917, Neurodyn II
Ibramed Equipamentos Medico, Sao Paulo, Brasil

6. Device Description

The StimaWELL 120MTRS has been designed for the use of medium frequency electro-therapy for muscle stimulation and pain relief therapy as well as for the warming and wellness application in the back region.

The device consists of a 12 channel (electrodes) Stimulation Mat, a Controller and a Remote Control Unit. Various accessories (see 11.3.2 below) support the operation of the StimaWELL. The warming is provided through controlled resistive heating of the stimulation mat.

Interaction with the device is via a touchscreen on the controller. Selection and set-up of various treatment sequences is via the controller touchscreen or can be recalled from chip cards. The patient can interact with the device by using the remote control unit. With that he can pause the treatment at any time and also adjust the overall intensity.

7. Indication for Use Statement

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

Russian mode: - Temporary relaxation of muscle spasms in back area
- Prevention or retardation of disuse atrophy of the lumbar paraspinal muscles

8. Substantial Equivalence Discussion

The following tables compares the Muscle Stimulator StimaWELL 120MTRS to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-1 – Comparison of Characteristics

Manufacturer	Pierenkemper GmbH	IBRAMED EQUIPAMENTOS MEDICOS
Trade Name	StimaWELL 120MTRS	Neurodyn II
510(k) Number	K181645	K131917
Product Code	GZJ IPF	GZJ IPF GZI
Regulation Number	882.5890 890.5850	882.5890 890.5850 882.5810
Regulation Name	Transcutaneous electrical nerve stimulator for pain relief Powered muscle stimulator	Transcutaneous electrical nerve stimulator for pain relief Powered muscle stimulator External functional neuromuscular stimulator
Indications for Use	N/A The StimaWELL is not used as a FES device	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.
	TENS mode: - 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
	Russian mode: - Temporary relaxation of muscle spasms in back area - Prevention or retardation of disuse atrophy of the lumbar paraspinal muscles	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
Technological characteristic	Medium-frequency alternating current (MFAC); modulated low-frequency alternating current	Medium-frequency alternating current (MFAC); Low-frequency alternating current (LFAC)

Electro-therapy Mechanism of Action	Transcutaneous muscle stimulation	Transcutaneous muscle stimulation
Operating Modes: TENS Russian FES	 Yes Yes No	 Yes Yes Yes
Setting of Mat Size	yes	N/A
Treatment Timer	20-30 minutes	Not publicly available
Automatic Shutoff	No	No
Device Material	ABS Plastic and LCD display	ABS Plastic and LCD display
Number of Channels	12	4
Technology Overview		
Software Micro-processor	Yes	Yes
Method of line current isolation	Double Isolation	Double Isolation
Patient leakage control-normal condition	< 0.041 mA	0.0347mA
Patient leakage control-single fault condition	< 0.063 mA	0.0162mA
Duration of stimulation	30 minutes	Not publicly available
Mode of operation	Continuous	Continuous
Energy Output	Yes	Yes
Sterile	No	No
Single-Use	No	No
AC Powered	100 to 240V 50/60Hz	100 to 240V 50/60Hz
Operating Environment	50°F – 104 °F (10° C – 40° C) 30%-90% relative humidity 700 hPa to 1060 hPa	41°F to 113°F (5°C- 45°C)
Storage and Transport Environment	14°F – 131 °F (-10 °C to 55 °C) 30%-90% relative humidity 500 hPa to 1060 hPa	59°F to 104°F (15°C- 40°C)
Complies with ISO 10993-1	Yes	Not publicly available
Electrical Safety Testing Passed	Yes	Yes

9. Comparison of Output Specifications (per Section 3)

Table 5-2 TENS Mode

Trade Name >	StimaWELL 120MTRS	Neurodyn II
a) Waveform (e.g., pulsed monophasic, biphasic)	biphasic	Not publicly available
b) Shape (e.g., rectangular, spike, rectified sinusoidal)	rectangular	Not publicly available
c) Maximum Output Voltage (specify units)		Not publicly available
@ 500 Ω,	58.7 Vpp (+/- 10 %)	Not publicly available
@ 2 kΩ	57.6 Vpp (+/- 10 %)	Not publicly available
@ 10 kΩ	68.3 Vpp (+/- 10 %)	Not publicly available
d) Maximum Output Current (specify units)		0 to 120mA peak to peak
@ 500 Ω,	58.7 mA (+/- 10 %)	124mA Tolerance not publicly available
@ 2 kΩ	14.4 mA (+/- 10 %)	110mA Tolerance not publicly available
@ 10 kΩ	3.42 mA (+/- 10 %)	39.2mA Tolerance not publicly available
e) Pulse Width (specify units)	500 ms to 5 ms	Not publicly available
f) Frequency (Hz)	1 Hz to 100 Hz	0.5 Hz to 250Hz
g) For interferential modes only: Beat Frequency (Hz)	N / A	Not publicly available
h) For multiphasic waveforms only:	N / A (Biphasic is noted above)	Not publicly available
Phase		
Symmetrical phases? (yes/no),		
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)		
i) Net Charge (µC per pulse) @ 500 Ω (If zero, state method of achieving zero net charge.)	N / A	Not publicly available
j) Maximum Phase Charge, (µC) @ 500 Ω	N / A	Not publicly available

Trade Name >	StimaWELL 120MTRS	Neurodyn II
k) Maximum Current Density. (mA/cm²) @ 500 Ω	3.87 mA/cm²	Not publicly available
l) Maximum Power Density, (W/cm²) @ 500 Ω (using smallest electrode conductive surface area) 15.18 cm²	0.11 W/cm²	0.038 W/cm²
m) Burst Mode (i.e., pulse trains)	N/A	Not publicly available
a. Pulses per burst		
b. Bursts per second		
c. Burst duration (seconds)		
d. Duty Cycle [Line (b) x Line (c)]		
n) ON Time (seconds)	N/A	Not publicly available
o) OFF Time (seconds)	N/A	Not publicly available
p) Additional features (if applicable)	N/A	

Table 5-3 Russian Mode

Trade Name >	StimaWELL 120MTRS	Neurodyn II
a) Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Not publicly available
b) Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Not publicly available
c) Maximum Output Voltage (specify units)		Not publicly available
@ 500 Ω,	62.7 Vpp (+/- 10 %)	Not publicly available
@ 2 kΩ	67.1 Vpp (+/- 10 %)	Not publicly available
@ 10 kΩ	68.7 Vpp (+/- 10 %)	Not publicly available
d) Maximum Output Current (specify units)		0 to 120mA peak to peak
@ 500 Ω,	62.7 mAp (+/- 10 %)	124mA Tolerance not publicly available
@ 2 kΩ	16.8 mAp (+/- 10 %)	110mA Tolerance not publicly available
@ 10 kΩ	3.44 mAp (+/- 10 %)	39.2mA Tolerance not publicly available
e) Pulse Width (specify units)	500 ms to 5 ms	Not publicly available
f) Frequency (Hz)	1 Hz to 100 Hz	0.5 Hz to 250 Hz
g) For interferential modes only: Beat Frequency (Hz)	N / A	Not publicly available
h) For multiphasic waveforms only:	N / A (Biphasic is noted above)	Not publicly available
Phase		
Symmetrical phases? (yes/no),		
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)		
i) Net Charge (µC per pulse) @ 500 Ω (If zero, state method of achieving zero net charge.)	N / A	Not publicly available
j) Maximum Phase Charge, (µC) @ 500 Ω	N / A	Not publicly available
k) Maximum Current Density, (mA/cm²) @ 500 Ω	4.13 mA/cm²	Not publicly available

l) Maximum Power Density, (W/cm²) @ 500 Ω (using smallest electrode conductive surface area)	0.13 W/cm²	0.038 W/cm²
m) Burst Mode (i.e., pulse trains)	N/A	Not publicly available
a. Pulses per burst		
b. Bursts per second		
c. Burst duration (seconds)		
d. Duty Cycle [Line (b) x Line (c)]		
n) ON Time (seconds)	N/A	Not publicly available
o) OFF Time (seconds)	N/A	Not publicly available
p) Additional features (if applicable)		

Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the StimaWell 120MTR and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Pierenkemper completed a number of non-clinical performance tests against applicable standards.

Table 5-2 – Performance Standards Testing Summary

Test		Pass / fail criteria	Results
1	Electrical safety	Compliance to IEC 60601-1:2005/AMD1:2012	Passed
2	Electromagnetic compatibility	Compliance to IEC 60601-1-2:2014	Passed
3	Nerve and muscle stimulators	Compliance to IEC 60601-2-10:2012	Passed
4	Biocompatibility	Compliance to ISO 10993-1, ISO 10993-5:2009, and ISO 10993-10:2002	Passed
5	Risk Management	Compliance to ISO 14971:2007	Passed
6	Software	Compliance to IEC 62304:2006	Passed
7	Usability	Compliance to IEC 62366:2007 (Ed. 1) + A1: 2014 and EN 60601-1-6:2013	Passed Passed

The StimaWELL 120MTRS passed all the testing in accordance with internal requirements, national standards, and international standards shown above, to support substantial equivalence of the subject device.

To demonstrate that the StimaWELL 120MTRS meets all design specifications and performance requirements, nonclinical bench testing was performed in accordance with the internal development

process in compliance with the recommendations of the FDA Guidance Document for Powered Muscle Stimulator 510(k)s [1999].

Also, internal verification and validation testing confirms that product specifications are met. The testing results support that the requirements for performance and electrical safety were met for the acceptance of the device. The StimaWELL 120MTRS passed all testing and supports the claims of substantial equivalence to the predicate device.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics but can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

The StimaWELL 120MTRS as designed and manufactured, is determined to be substantially equivalent to the predicate device.