August 26, 2022

Gimer Medical Co., Ltd.
% Anita Chen
RA
ZhengCheng Limited Company
238 No.19. 335 Lane, Fu-Xi Road, Shulin District
New Taipei City, Taiwan 238
Taiwan

Re: K213802
Trade/Device Name: StimOn™ Pain Relief System (GM2439)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: July 5, 2022
Received: July 25, 2022

Dear Anita Chen:

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,

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)*
K213802

Device Name
StimOn™ Pain Relief System (GM2439)

Indications for Use *(Describe)*
StimOn™ Pain Relief System (GM2439) is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical or post-traumatic 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.

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

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510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92.

The assigned 510(k) Number: K213802

1.	Manufacturer	Gimer Medical Co., Ltd.
	Mail Address	Address: 9F.-5, No. 97, Sec. 1, Xintai 5th Road, Xizhi District, New Taipei City, Taiwan Tel. +886-2-2697-2680 Fax. +886-2-2697-2670 Website: http://www.gimermed.com/
	Manufacturer address	Address: 9F.-7 and 9F.-8, No. 97, Sec. 1, Xintai 5th Road, Xizhi District, New Taipei City, Taiwan
	Contact Person	Mrs. Anita Chen/ Regulatory Advisor of Gimer Medical Co., Ltd.
	Phone:	+886(0) 939-855-759
	E-mail:	Anita9104303@gmail.com
	Date Prepared	8/26/22
2	Device Name	
	Trade Name:	StimOn™ Pain Relief System (GM2439)
	Common or usual name	Nerve stimulator
	Product Code	GZJ
	Regulation Name	Transcutaneous electrical nerve stimulator for pain relief
	CFR Classification	CFR Part 882.5890
	Device Class	II
	Classification Panel	Neurology
3	Primary Predicate Device	
	510(k) number:	K081835
	Trade or proprietary or	Bioinduction Acticare HFT/HFI

	model name:	
	Manufacturer:	Bioinduction Limited (178-180 Hotwell Road, BRISTOL, BS8 4RP, United Kingdom, Telephone number: +44 117 377 5275, Fax number: +44 117 377 5405)
	Secondary Predicate Device 510(k) number:	K161091
	Trade or proprietary or model name:	STIMPOD NMS460 Nerve Stimulator
	Manufacturer:	XAVANT TECHNOLOGY (PTY) LTD Street Address: Unit 102 The Tannery Industrial Park 309 Derdepoort Road Silverton City: Pretoria State/Province: Gauteng Country: South Africa
4	Reference Device of Electrode Pad (Accessary) 510(k) number:	K180865
	Trade or proprietary or model name:	ZMI Self-Adhesive Electrodes
	Manufacturer:	ZMI Electronics, Ltd. 6F-1, 286-4, Shin Ya Road Kaohsiung, TW 806
	Reference Device for OTC usability 510(k) number:	K180943
	Trade or proprietary or model name:	BioWaveGO
	Manufacturer:	Biowave Corporation 8 Knight Street, Suite 201 Norwalk, CT 06851

5	Device Description:	StimOn™ Pain Relief System (GM2439) is a hand-held stimulator designed to pass electrical signals via surface electrodes through the skin to the underlying nerves. It may be used as a TENS device to aid the blocking of pain signals traveling to the brain.

6.	Indications for Use:	StimOn™ Pain Relief System (GM2439) is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical or post-traumatic pain.
7.	Technological Characteristics and Substantial Equivalence Comparison with Predicates:	A comparison of the device features, intended use, and other information demonstrates that the Product name is substantially equivalent to the predicate device as summarized in *Table 1*. The differences raise no new question of safety and effectiveness.

Table 1. Comparison table

Description	**Subject Device**	**Predicate Device**	**Predicate Device**
510(k) Number	K213802	K081835	K161091
Manufacture	Gimer Medical Co., Ltd	Bioinduction Limited	XAVANT TECHNOLOGY (PTY) LTD
Product code	GZJ	GZJ, IPF	GZJ
Device Name	StimOn™ Pain Relief System (GM2439)	Bioinduction Acticare HFT/HFI	STIMPOD NMS460 Nerve Stimulator
Indications for use	StimOn™ Pain Relief System (GM2439) is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical or	As a Transcutaneous Electronic Nerve Stimulation (TENS) device for: the symptomatic relief of chronic intractable pain, and as an adjunctive treatment	The STIMPOD NMS460 Nerve Stimulator is a Transcutaneous Electrical Nerve Stimulation(TENS) device used for symptomatic relief

	post-traumatic pain	in the management of post-surgical or post-traumatic pain. As a Neuromuscular Electrostimulation (NMS) device for: the relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis and to maintain or increase the range of motion.	and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain problems, as well as an adjunct for pain control due to rehabilitation.
Prescription/over-the counter use	Over-the-counter use	Prescription	Prescription
Power Supply	One 3.7V, 125mAh rechargeable Lithium polymer battery	Not publicly available	4 x AAA alkaline batteries
Treatment Timer Maximum	15 minutes	Not publicly available	99 minutes

Number of Output Modes	1 (RF Mode)	Not publicly available	1
Number of Waveforms	1	Not publicly available	2 (Monophasic, Biphasic with offset)
Waveform	Biphasic(Sine Wave)	Not publicly available	Monophasic square wave/Hybrid RF wave
RF Stimulation Mode	Transcutaneous Pulsed Radio-frequency (PRF) mode	Not publicly available	Hybrid RF waveform which consists of a Monophasic Square Wave with a superimposed Radio Frequency waveform
RF Frequency	500 kHz fixed	Not publicly available	160kHz fixed
Burst Time	25ms	Not publicly available	100µs, 200µs
Burst Frequency	2Hz	Not publicly available	1,2,5,10 Hz
Electrode Contact	Hydrogel pad	Not publicly available	Probe electrode
Load Impedance	1 k Ohm, Over this load, the system will automatically shut off.	Not publicly available	7 K Ohm

Maximum Output Voltage	7.4 V+/-10% 6.6 V +/- 20% @ @500Ω with Electrode Pad	Not publicly available	220 V
Maximum Output Current	14.8 mA (Peak)@500Ω 13.2 mA (Peak)@500Ω with Electrode Pad	Not publicly available	43.7mA @500Ohm
Maximum Average Current (Over primary phase)	9.43 mA (Peak) @500Ω 8.41mA(Peak) @500Ω with Electrode	Not publicly available	29.85mA@500Ohm
Maximum Average Power Density (Smallest electrode area) "P"	112.81 µW/mm^2 @500Ohm with Electrode	Not publicly available	71.5µW/mm^2 @500Ohm
Maximum Current (RMS) Density (mA/mm^2)	0.0242 mA /mm^2 @500Ω with Electrode	Not publicly available	93.28µA/mm^2 @500Ohm
Net Charge	The theoretical value is 0.	Not publicly available	6.06µC
Maximum averagephase charge [µC]	0.00942µC	Not publicly available	6.06µC

Summary of the technological characteristics of subject and predicate devices:

The StimOn™ Pain Relief System (GM2439) and Bioinduction Acticare are the same in use for body contact with the hydrogel pad. The other predicate STMPOD NMS460 is using the probe electrode instead. The subject and predicate devices have available RF stimulation modes. The slight differences between these three devices are the burst time, burst frequency, and RF frequency and the differences between the three devices are treatment timer maximum, power source, load impedance and maximum output.

The StimOn™ Pain Relief System (G2439) only has a single stimulation treatment mode at 500KHz, and impedance ranges from 100 to 1000 ohms to simplify the operation of device. Comparison of RF Stimulating Options (RF mode) of StimOn™ Pain Relief System (GM2439), and two predicates of Bioinduction Acticare and STMPOD NMS460 in waveform, RF Frequency, Burst time, Burst Frequency in Table1.

It indicated that from a safety perspective, the StimOn™ Pain Relief System (GM2439) its maximum average power density is within the value range of the two predicates (above STIMPOD and below Acticare). Thus, in the RF mode of energy output mechanism, it could infer that the treatment efficacy of StimOn™ Pain Relief System (GM2439) is sufficient to compare with the two predicate device and the differences between the subject and predicate(s) do not impact safety and effectiveness.

8. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device.

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety,
- 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 60601-1-11: Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10: Medical electrical equipment – Part 2: Particular requirements for the

basic safety and essential performance of nerve and muscle stimulators

• ASI/AAMI NS4: Medical Electrical Equipment Transcutaneous electrical nerve stimulators

Biocompatibility and Performance of electrodes:

The subject device utilizes electrodes cleared under K180865. Performance data (e.g. impedance, current dispersion, adhesion and electrode stability) and biocompatibility testing for the electrodes was leveraged from K180865.

Animal testing

No animal studies have been required for these devices.

Clinical testing

No Human Clinical Performance Testing have been required for StimOn™ Pain Relief System (GM2439) device for this application.

Usability

The StimOn™ Pain Relief System (GM2439) is similar in intended use and technical specifications to the BioWaveGO (K180943), which was cleared for over-the-counter (OTC) use. The subject device also complies with IEC 62366: Medical devices Part 1: Application of usability engineering to medical devices.

9. Conclusion

StimOn™ Pain Relief System (GM2439) has the same intended use as the predicate device. Although there is a slightly different technological design, as compared to the predicate, the conclusions drawn from the test data demonstrate that the device is as safe and as effective as the legally marketed device identified in the submission. Therefore, the subject device is “Substantially Equivalent” to the predicate devices.