June 12, 2020

Electronic Pulse Stimulator
℅ Salon Chen
System engineer
IMD Medical & Drug technology service institutions
Tianbao Office Room 225, Sha Tai Road No.209
Shenzhen city, 518117 Cn

Re: K192201
Trade/Device Name: Electrical Stimulator System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN
Dated: June 8, 2020
Received: June 8, 2020

Dear Salon 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,

Vivek Pinto, PhD
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)*
K192201

Device Name
Electrical Stimulator System

Indications for Use *(Describe)*

TENS (Modes 1 and 6)

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS (Modes 2, 3, 4 and 5)

To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

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

1. Submitter's Identification:

- Company Name: Gymmax Technology Shenzhen Co., Ltd.
- Establishment Registration Number: 3007689716
- Address: East 5F, A2 Building, Huimingsheng DingFeng Technology Park, Fuhai Street, Fuyong Town, Baoan District, 518103 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
- Phone:+86-755-2912-4050
- Fax: +86-755-2912-4050
- Contact Person(Title):Benson Wang (General Manager)
- E-mail：benson_gmx@qq.com
- Date of Preparation: June,01,2020

2. Name of the Device:

- Electrical Stimulator System
- Models: GME-SS-001、GMT-SS-001、GMM-SS-001

3. Common Name and Classification:

- Stimulator, Nerve, Transcutaneous, Over-The-Counter
- Classification Product Code: NUH,NGX and NYN
- Regulation Number:21 CFR 882.5890
- Class: II

4. Predicate Device Information:

- 510(k) Number: K153520
- Predicate Device Name: Electronic Pulse Stimulator
- Manufacturer: JKH Health Co., Ltd
- This predicate has not been subject to a design-related recall

- No reference devices were used in this submission.

5. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person(Title):Salon Chen (System engineer)
- E-mail：33999439@qq.com

6. Device Description

The Electrical Stimulator System delivers electric pulses to the user's body areas such as the back, neck, and foot through the electrodes. The portable and compact device has multiple modes of different pulse frequencies, including transcutaneous electrical nerve stimulation (TENS) and power muscle stimulation (PMS) that is also called Electrical Muscle Stimulation (EMS). It includes the operating elements of an ON/OFF button, intensity increase button, intensity decrease button, mode selection button, and can be attached and detached to electrodes.

The electrodes cleared include the electrode pads and electrode garments, which may be packaged separately and/or together with the subject device.

The associated accessories include:

Arm Pad (34x56mm±2mmx2) * 1

Abdominal Pad (34x56mm±2mmx6) * 1

Gel Pad (34x56mm±2mm,produced by GMDASZ with K092546) * 8

USB Cable * 1

Operating Instruction * 1

7. Indications for Use

TENS (Modes 1 and 6)

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS (Modes 2, 3, 4 and 5)

To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

8. Comparison to the predicate device

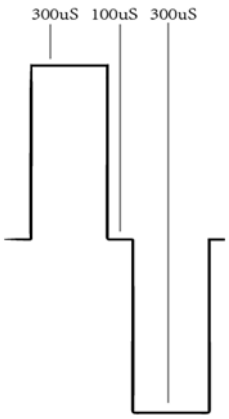
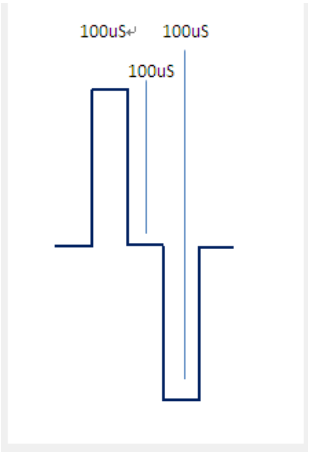
Electrical stimulation is the technological principle for both the subject and predicate device. In the EMS modes, electronic pulses are sent through electrode pads to passively exercise the affected muscle. When your muscle receives this signal, it contracts and flexes naturally, as it would during physical exercise. And like with physical exercise, when the pulse ceases, the muscle relaxes and the cycle can start over again. In the TENS modes, the gentle electrical pulses were sent through electrode pads and into skin to block or shut out the pain message from ever reaching the brain from the source of the pain.

Table 1: Technological Characteristics

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Gymmax Technology Shenzhen Co., Ltd.	JKH Health Co., Ltd	/
Device Name	Electrical Stimulator System	Electronic Pulse Stimulator	/
Classification Product Code	NUH	NUH	SE
Subsequent Product Codes	NGX, NYN	NGX, NYN	SE
Regulation	21 CFR 882.5890	21 CFR 882.5890	SE
Classification Name	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	SE
Class	2	2	SE
Prescription or OTC	OTC	OTC	SE
Functions and design	Electrical stimulation	Electrical stimulation	SE
Power Source(s)	Rechargeable battery	Rechargeable battery	SE

Intended Use	TENS (Modes 1and 6) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS (Modes 2,3,4,5) To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.	TENS (Modes 1, 2, 4, 5, 6) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS (Modes 1 and 3) To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.	SE

Table 2: Basic Unit Characteristics Comparison Table.

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Electrical Safety	Conformance with IEC 60601-1	Conformance with IEC 60601-1	SE
EMC	Conformance with IEC 60601-1-2	Conformance with IEC 60601-1-2	SE
Biocompatiblity	Conformance with ISO 10993-1	Conformance with ISO 10993-1	SE
Performance	Conformance with IEC 60601-2-10:2012 medical electrical equipment - part 2-1	Conformance with IEC 60601-2-10:2012 medical electrical equipment - part 2-1	SE
Waveform	Biphasic, symmetrical	Biphasic, symmetrical	SE
Pulse width	300µs-100µs -300µs 	100µs -100µs -100µs 	Similar (Note 1)
Maximum output voltage (volts+/-20%) at 500Ω	Mode 1: 46 Mode 2: 43.2 Mode 3: 29.2 Mode 4: 29.2 Mode 5: 44 Mode 6: 29.2	Mode 1: This mode cycles the following modes Mode 2: 39.2 Mode 3: 64 Mode 4: 56.8 Mode 5: 33.2 Mode 6: 31.6	Similar (Note 1)

Maximum output voltage (volts+/-20%) at 2KΩ	Mode 1: 75 Mode 2: 80 Mode 3: 64 Mode 4: 63 Mode 5: 82 Mode 6: 64	Mode 1: This mode cycles the following modes Mode 2: 82.4 Mode 3: 84 Mode 4: 79.2 Mode 5: 70.4 Mode 6: 67.2	Similar (Note 1)
Maximum output voltage (volts+/-20%) at 10KΩ	Mode 1: 90 Mode 2: 90 Mode 3: 86 Mode 4: 90 Mode 5: 90 Mode 6: 90	Mode 1: This mode cycles the following modes Mode 2: 129 Mode 3: 120 Mode 4: 84.8 Mode 5: 121 Mode 6: 124	Similar (Note 1)
Maximum output current (mA+/-20%) at 500Ω	Mode 1: 92 Mode 2: 86.4 Mode 3: 58.4 Mode 4: 58.4 Mode 5: 88 Mode 6: 58.4	Mode 1: This mode cycles the following modes Mode 2: 78.4 Mode 3: 128 Mode 4: 113.6 Mode 5: 64.4 Mode 6: 63.2	Similar (Note 1)

Maximum output current (mA+/-20%) at 2KΩ	Mode 1: 37.5 Mode 2: 40 Mode 3: 64 Mode 4: 31.5 Mode 5: 41 Mode 6: 32	Mode 1: This mode cycles the following modes Mode 2: 41.2 Mode 3: 42 Mode 4: 39.6 Mode 5: 35.2 Mode 6: 33.6	Similar (Note 1)
Maximum output current (mA+/-20%) at 10KΩ	Mode 1: 9 Mode 2: 9 Mode 3: 8.6 Mode 4: 9 Mode 5: 9 Mode 6: 9	Mode 1: This mode cycles the following modes Mode 2: 12.9 Mode 3: 12 Mode 4: 8.5 Mode 5: 12.1 Mode 6: 12.4	Similar (Note 1)
Pulse period (mSec)	20~500	10~833	Similar (Note 1)
Frequency(Hz)	Mode 1: 5 Mode 2: 20 Mode 3: 50 Mode 4: 50 Mode 5: 10~50 Mode 6: 2HZ（50Hz mixed with 2Hz）	Mode 1: This mode cycles the following modes Mode 2: 69.4 Mode 3: 13.0~52.1 Mode 4: 1.2 Mode 5: 96.2 Mode 6: 96.2	Similar (Note 1)

Maximum Phase charge(μC) at 500Ω	Mode 1: 27.6 Mode 2: 25.92 Mode 3: 17.52 Mode 4: 17.52 Mode 5: 26.4 Mode 6: 17.52	Mode 1: This mode cycles the following modes Mode 2: 15.1 Mode 3: 25.6 Mode 4: 18.2 Mode 5: 12.8 Mode 6: 10.1	Similar (Note 1)
Maximum charge density(mA/cm^2) at 500Ω	Mode 1: 0.325(arm)/0.112(abs) Mode 2: 0.61(arm)/0.21(abs) Mode 3: 0.653(arm)/0.225(abs) Mode 4: 0.653(arm)/0.225(abs) Mode 5: 0.435~0.984(arm)/ 0.15~0.34(abs) Mode 6: 0.131(arm)/0.045(abs)	Mode 1:This mode cycles the following modes Mode 2: 2.18 Mode 3: 3.56 Mode 4: 3.16 Mode 5: 1.84 Mode 6: 1.76	Similar (Note 1)
Maximum average power density(mw/cm^2) at 500Ω	Mode 1: 14.94(arm)/5.15(abs) Mode 2: 26.33(arm)/9.08(abs) Mode 3: 19.07(arm)/6.57(abs) Mode 4: 19.07(arm)/6.57(abs) Mode 5: 19.15~43.28(arm)/ 6.6~14.92(abs) Mode 6: 3.81(arm)/1.31(abs)	Mode 1: This mode cycles the following modes Mode 2: 1.14 Mode 3: 0.64~2.56 Mode 4: 0.03 Mode 5: 1.13 Mode 6: 0.85	Similar (Note 1)

Note 1:

As shown in the above comparison Table, the six modes of the subject device, have the technical characteristics (such as maximum output voltage, maximum output current, maximum current density, and maximum average power density) in similarity to the predicate device. Accordingly, we are substantially equivalent to the predicate device Electronic Pulse Stimulator (K153520).

Design and Technology – The basic design and technology of providing electrical stimulation is the same or similar.

Performance and Specifications – The subject device has similar electrical stimulation and specifications to the predicate device.

Indications – The indications are same.

Review of Differences：

Pulse Width

The difference in pulse width between the subject device and the predicate device is having different sensation when delivered to human body.Different pulse width will lead to different output charge.The bigger pulse width has more energy than smaller pulse width. A large mount of charge will gives more obvious sensation to human body, but the charge is still within the required safety performance range according to the safety calculation.Therefore the difference does not raise different types of questions of safety and effectiveness as compared to the predicate devices.

Maximum Phase Charge

The reason that the subject device's phase charge is higher than the predicate is because the allowed voltage is higher than predicate device's at 500Ω. However, the subject device's phase charge is still in the safety range. In addition, the negative phase charge and the positive phase charge are always balanced out. Therefore, the difference does not raise different types of questions of safety and effectiveness as compared to the predicate devices.

Frequency range

Frequency for the subject device is 2~50Hz and it falls into the subject device frequency of 1.2~96.5Hz. So the difference doesn't raise different types of questions of safety and effectiveness.

As demonstrated, the differences between the subject and predicate devices do not affect the intended use or alter the fundamental technology of the device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, safety, and effectiveness as the predicate device.

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

1) Electrical safety

IEC60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

2) Electromagnetic compatibility(EMC)

IEC 60601-1-2:2014 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests.

3) Basic Safety And Essential Performance

IEC 60601-1-11 Edition 2.0 2015-01 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 60601-2-10:2012 medical electrical equipment - part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

IEC 60601-1-6 Edition 3.1 2013 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.

4) Software Verification and Validating Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

5) Biocompatibility testing

ISO 10993-1:2009 Biological evaluation of medical devices-Parts 1: Evaluation and testing.

ISO 10993-5:2009 Biological evaluation of medical devices-Parts 5: Tests for In Vitro cytotoxicity.

ISO 10993-10:2010 Biological evaluation of medical devices-Parts 10: Tests for irritation and skin sensitization.

9. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The proposed device is the same as the predicate device but the two devices are different. A series of safety and performance tests were conducted on the subject device:

Shelf Life

Biocompatibility

Software Validation

Electromagnetic compatibility and electrical safety

Function test (Including output waveforms, stimulation parameters and current distribution on the electrodes)

All the test results demonstrate Electrical Stimulator System meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate devices.

10. Clinical Tests Performed

No clinical test data was used to support the decision of substantial equivalence.

11. Conclusion

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate devices.