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.


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 J. Pinto -S

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
Indications for Use

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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

<table>
<thead>
<tr>
<th>Elements of Comparison</th>
<th>Proposed Device</th>
<th>Predicate Device</th>
<th>Judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name</td>
<td>Gymmax Technology Shenzhen Co., Ltd.</td>
<td>JKH Health Co., Ltd</td>
<td>/</td>
</tr>
<tr>
<td>Device Name</td>
<td>Electrical Stimulator System</td>
<td>Electronic Pulse Stimulator</td>
<td>/</td>
</tr>
<tr>
<td>Classification Product Code</td>
<td>NUH</td>
<td>NUH</td>
<td>SE</td>
</tr>
<tr>
<td>Subsequent Product Codes</td>
<td>NGX, NYN</td>
<td>NGX, NYN</td>
<td>SE</td>
</tr>
<tr>
<td>Regulation</td>
<td>21 CFR 882.5890</td>
<td>21 CFR 882.5890</td>
<td>SE</td>
</tr>
<tr>
<td>Classification Name</td>
<td>Transcutaneous electrical nerve stimulator for pain relief</td>
<td>Transcutaneous electrical nerve stimulator for pain relief</td>
<td>SE</td>
</tr>
<tr>
<td>Class</td>
<td>2</td>
<td>2</td>
<td>SE</td>
</tr>
<tr>
<td>Prescription or OTC</td>
<td>OTC</td>
<td>OTC</td>
<td>SE</td>
</tr>
<tr>
<td>Functions and design</td>
<td>Electrical stimulation</td>
<td>Electrical stimulation</td>
<td>SE</td>
</tr>
<tr>
<td>Power Source(s)</td>
<td>Rechargeable battery</td>
<td>Rechargeable battery</td>
<td>SE</td>
</tr>
<tr>
<td>Intended Use</td>
<td>TENS (Modes 1 and 6)</td>
<td>TENS (Modes 1, 2, 4, 5, 6)</td>
<td>PMS (Modes 2, 3, 4, 5)</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
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<td>PMS (Modes 1 and 3)</td>
</tr>
<tr>
<td></td>
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<td>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.</td>
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</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Table 2: Basic Unit Characteristics Comparison Table.

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

<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode 1</td>
<td>75</td>
</tr>
<tr>
<td>Mode 2</td>
<td>80</td>
</tr>
<tr>
<td>Mode 3</td>
<td>64</td>
</tr>
<tr>
<td>Mode 4</td>
<td>63</td>
</tr>
<tr>
<td>Mode 5</td>
<td>82</td>
</tr>
<tr>
<td>Mode 6</td>
<td>64</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode 1</td>
<td>90</td>
</tr>
<tr>
<td>Mode 2</td>
<td>90</td>
</tr>
<tr>
<td>Mode 3</td>
<td>86</td>
</tr>
<tr>
<td>Mode 4</td>
<td>90</td>
</tr>
<tr>
<td>Mode 5</td>
<td>90</td>
</tr>
<tr>
<td>Mode 6</td>
<td>90</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode 1</td>
<td>92</td>
</tr>
<tr>
<td>Mode 2</td>
<td>86.4</td>
</tr>
<tr>
<td>Mode 3</td>
<td>58.4</td>
</tr>
<tr>
<td>Mode 4</td>
<td>58.4</td>
</tr>
<tr>
<td>Mode 5</td>
<td>88</td>
</tr>
<tr>
<td>Mode 6</td>
<td>58.4</td>
</tr>
</tbody>
</table>

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\(\times 50\)Hz 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/cm²) 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/cm²) 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**


2) **Electromagnetic compatibility (EMC)**


3) **Basic Safety And Essential Performance**


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.


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.


9. **Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence**

   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.