June 10, 2024

Gymmax Technology Shenzhen Co., Ltd.
% Salon Chen
System engineer
IMD Medical & Drug technology service institutions
Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District
Dongguan, Guangdong 523039
China

Re: K240108
Trade/Device Name: Wrap Accessory Electrodes (GMX-ABSBELT01, GMX-ABSBELT02, GMX-WRIST01, GMX-ELBOW01, GMX-LEG 01, GMX-ANKLE01, GMX-KNEE01, GMX-FOOT PAD 01, GMX-GLOVES 01, SHOULDER01, GMX-NCK01)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: May 13, 2024
Received: May 14, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240108

Device Name

Wrap Accessory Electrodes (GMX-ABSBELT01、GMX-ABSBELT02、GMX-WRIST01、GMX-ELBOW01、GMX-LEG 01、GMX-ANKLE01、GMX-KNEE01、GMX-FOOT PAD 01、GMX-GLOVES 01、SHOULDER01、GMX-NCK01)

Indications for Use *(Describe)*

The Wrap Accessory Electrodes are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The wrap accessory electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The wrap accessory electrodes, made up of conductive silicone rubber, can be used for the stimulation on the body areas such as abdomen, neck, shoulder, elbow, leg, hand, wrist, ankle, knee and foot .

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

1. **Submitter's Identification:**

- Company Name: Gymmax Technology Shenzhen Co., Ltd.
- Establishment Registration Number: 3007689716
- Address:5F 4th Bldg., Heping Complex (4th Bldg. Huimingsheng Technology Park) Fuhai Subdistrict, Baoan District Shenzhen City, Guangdong Province 518103 P.R.C.
- 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: May 04, 2024

2. **Common Name and Classification:**

- Regulation Name: Cutaneous Electrode
- Classification Product Code: GXY
- Regulation Number: 21 CFR 882.1320
- Regulatory Class: Class II
- Review Panel: Neurology
- Trade Name: Wrap Accessory Electrodes

3. **Predicate Device Information1:**

- **510(k) Number**: K210383
- **Predicate Device Name:** Wrap Accessory Electrodes
- **Manufacturer:** Hi-Dow International Inc.
- **Intended Use:**

The Wrap Accessory Electrodes are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The wrap accessory electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The wrap accessory electrodes,

made up of conductive silicone rubber, can be used for the stimulation on the body areas such as back, neck, shoulder, elbow, wrist, knee and foot.

4. Predicate Device Information2:

- **510(k) Number:** K190617
- **Predicate Device Name:** Wrap accessory electrodes
- **Manufacturer**: Hi-Dow International Inc.
- **Intended Use:**

Wrap accessory electrodes, available in a glove style or socks style, are cutaneous electrodes intended to be used with legally marketed TENS or EMS stimulating devices. The Wrap accessory electrodes are non-sterile reusable OTC conductive garments that are intended to deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include the hands (gloves) and feet (socks). It is intended for adult patients.

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
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

6. Device Description

Wrap Accessory Electrodes with GMX-ABSBELT01、GMX-ABSBELT02、GMX-WRIST01、GMX-ELBOW01、GMX-LEG 01、GMX-ANKLE01、GMX-KNEE01、GMX-FOOT PAD 01、GMX-GLOVES 01、SHOULDER01、GMX-NCK01, are intended to be used with legally Marketed transcutaneous electrical nerve stimulators or powered muscle stimulators which could be used in place of traditional cutaneous electrode patches. The different series of model means different placement of the Wrap Accessory Electrodes. The wrap accessory electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact.

The wrap accessory electrodes, made up of conductive silicone rubber, can be used for the stimulation on the body areas such as abdomen, neck, shoulder, elbow, leg, Hand, wrist, ankle, knee and foot.

7. Indications for Use

The Wrap Accessory Electrodes are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The wrap accessory electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The wrap accessory electrodes, made up of conductive silicone rubber, can be used for the stimulation on the body areas such as abdomen, neck, shoulder, elbow, leg, Hand, wrist, ankle, knee and foot.

8. Comparison to the predicate device

8.1 Table 1 General Comparison

Elements of Comparison	Proposed Device K240108	Predicate Device 1 K210383	Predicate Device 2 K190617	Judgment
Company Name	Gymmax Technology Shenzhen Co., Ltd.	Hi-Dow International Inc.	Hi-Dow International Inc.	/
Device Name	Wrap Accessory Electrodes	Wrap Accessory Electrodes	Wrap Accessory Electrodes	/
Classification Product Code	GXY	GXY	GXY	SE
Regulation	21 CFR 882.1320	21 CFR 882.1320	21 CFR 882.1320	SE
Classification Name	Electrode, Cutaneous	Electrode, Cutaneous	Electrode, Cutaneous	SE
Class	2	2	2	SE
Prescription or OTC	OTC	OTC	OTC	SE

Intended Use	The Wrap Accessory Electrodes are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The wrap accessory electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The wrap accessory electrodes, made up of conductive silicone rubber, can be used for the stimulation on the body areas such as abdomen, neck, shoulder, elbow, leg, Hand, wrist, ankle, knee and foot.	The Wrap Accessory Electrodes are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The wrap accessory electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. The wrap accessory electrodes, made up of conductive silicone rubber, can be used for the stimulation on the body areas such as back, neck, shoulder, elbow, wrist, knee and foot.	Wrap accessory electrodes, available in a glove style or socks style, are cutaneous electrodes intended to be used with legally marketed TENS or EMS stimulating devices. The Wrap accessory electrodes are non-sterile reusable OTC conductive garments that are intended to deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include the hands (gloves) and feet (socks). It is intended for adult patients.	Note1

Table 1 General Comparison

Note 1: As shown in the above comparison Table，Proposed Device adds and can be used for the stimulation on the body areas such as abdomen, leg, ankle and foot. Electronic pulses are sent through electrode pads to passively exercise the affected muscle. EMS sends comfortable impulses through your skin that stimulates the nerves in the treatment area, in the same way, TENS or EMS is effect in other areas of the body areas, they are all used to deliver the stimulation signals generated by electrical stimulator to the body surface, therefore, the difference does not raise new questions of safety and effectiveness as compared to the predicate devices.

8.2Table 2 Safety factor & Performance Comparison

Safety factor & Performance	Proposed Device	Predicate Device1	Predicate Device2	Judgment
impedance per area (Ω/in.^{2}) as a worst-case condition	12.5	/	/	Note 2
Biocompatiblity	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1	SE

Table 2 Safety factor & Performance Comparison

Note 2: Electrode conductive area and Impedance Parameters Although the subject device has 12.5 Ω per inch, which is different from the predicate device, “Maximum Average Current Density” and “Maximum Peak Power Density” property are similar and do not raise new questions of safety or effectiveness. The standard of "Maximum Average Current Density" refers to “IEC60601-2-10 Clause 201.4.2” and the standard of “Maximum Peak Power Density” refer to “Guidance Document for Powered Muscle Stimulator 510K Section 3.” Indicating similar performance and safety between subject device and predicate device. Otherwise, the subject devices are complying with ISO 10993 requirements. So, the differences of the function specifications will not raise any safety or effectiveness issue. For detailed measurement data, please refer to the above table. The subject device is Substantially Equivalent to the predicate device.

Electrical Stimulator System has applied for K232439 with Models: GMX-007 and GMX-006, Electrical Stimulator System with Wrap Accessory Electrodes have been tested with below:

1) Basic Safety and Essential Performance

IEC 60601-1-11:2020: 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 +A1:2016+A2:2023medical electrical equipment - part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

IEC 60601-1-6 :2010+A1:2013+A2:2020 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.

2) Biocompatibility testing

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

ISO 10993-10:2021 Biological evaluation of medical devices-Parts 10: Tests for skin sensitization

ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation

3) Maximum output voltage (volts+/-20%) at 500Ω、Maximum output voltage (volts+/-20%) at 2KΩ、Maximum output voltage (volts+/-20%) at 10KΩ、Maximum output current (mA+/-20%) at 500Ω、Maximum output current (mA+/-20%) at 2KΩ、Maximum output current (mA+/-20%) at 10KΩ

Safety factor & Performance	Proposed Device
Maximum output voltage (volts+/-20%) at 500Ω	TENS 1:112 TENS 2: 114 STIM1:116 STIM2:116 STIM3:76 STIM4: 70
Maximum output voltage (volts+/-20%) at 2KΩ	TENS 1: 250 TENS 2: 240 STIM1: 250 STIM2: 250 STIM3: 158 STIM4: 146
Maximum output voltage (volts+/-20%) at 10KΩ	TENS 1: 300 TENS 2: 286 STIM1: 310 STIM2: 308 STIM3: 278 STIM4: 276
Maximum output current (mA+/-20%) at 500Ω	TENS 1: 224 TENS 2: 228 STIM1: 232 STIM2: 232 STIM3: 152 STIM4：140
Maximum output current (mA+/-20%) at 2KΩ	TENS 1:125 TENS 2: 120 STIM1: 125 STIM2: 125 STIM3:79 STIM4: 73

Maximum output current (mA+/-20%) at 10KΩ	TENS 1: 30 TENS 2: 28.6 STIM1: 31 STIM2:30.8 STIM3: 27.8 STIM4: 27.6
Pulse period (mSec)	20~200
Frequency (Hz)	TENS 1: 33 TENS 2: 5 STIM1:37 STIM2:25 STIM3: 5 STIM4: 50
Maximum Phase charge (μC) at 500Ω	TENS 1: 11 TENS 2: 11 STIM1: 11.4 STIM2: 10.6 STIM3: 22.8 STIM4: 20.4
Maximum charge density (mA/cm^2) at 500Ω	TENS 1: 0.024 TENS 2: 0.01 STIM1:0.027 STIM2: 0.021 STIM3: 0.021 STIM4: 0.059
Maximum average power density (mw/cm^2) at 500Ω	TENS 1: 1.33 TENS 2: 0.554 STIM1: 1.54 STIM2: 1.13 STIM3: 0.793 STIM4: 2.01

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:

Biocompatibility

Electromagnetic compatibility and electrical safety

Function test with Maximum resistance value、Minimum resistance value、Maximum output

voltage、Maximum output current、Maximum Phase charge、Maximum charge density、Maximum average power density、hot spot test and impedance per area.

All the test results demonstrate Wrap Accessory Electrodes 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.