March 8, 2022

Shenzhen Jianfeng Electronic Technology Co. Ltd.
Feng Wen
General Manager
902, 903 Jialingyu Industrial Building, Da Pu Road
Houting Village, Shajing Town, Baoan District
Shenzhen, Guangdong 518104
China

Re: K213741
Trade/Device Name: TENS & EMS Device (Model: FM-B2403A)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: December 17, 2021
Received: December 17, 2021

Dear Feng Wen:

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)*
K213741

Device Name
TENS & EMS Device (Model: FM-B2403A)

Indications for Use *(Describe)*
TENS:
The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.

EMS:
The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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

K213741

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Type of 510(k) submission: Traditional
   Date of the summary prepared: Feb-17-2022

2. Submitter's Information

Submitter: SHENZHEN JIAN FENG ELECTRONIC TECHNOLOGY CO., LTD.
Address: 902, 903 Jialingyu Industrial Building, Da Pu Road, Houting Village, Shajing Town, Baoan District, Shenzhen City, Guangdong Province, 518104, China.
Contact Person: Feng Wen
Email: wenfeng@fzjhealth.com
Tel: +86-755-33858361 Fax: +86-755-33858360

Application Correspondent
Company: SHENZHEN JIAN FENG ELECTRONIC TECHNOLOGY CO., LTD.
Address: 902, 903 Jialingyu Industrial Building, Da Pu Road, Houting Village, Shajing Town, Baoan District, Shenzhen City, Guangdong Province, 518104, China.
Contact Person: Feng Wen
Title: General Manager
Email: wenfeng@fzjhealth.com
Tel: +86-755-33858361 Fax: +86-755-33858360

3. Subject Device Information
   Trade Name: TENS & EMS Device (Model: FM-B2403A)
   Common Name: TENS, EMS, Stimulator for pain relief;
   Classification Name: Powered muscle stimulator; Transcutaneous electrical nerve stimulator for pain relief; Nerve muscle stimulator
   Review Panel: Physical Medicine; Neurology
   Product Code: NUH, NGX
   Regulation Number: 21 CFR 882.5890, 21 CFR 890.5850
   Device Classification: Class II
   Use: Over-the-Counter Use (OTC)

4. The Predicate Device Information

Basic Information	Predicate Device
Manufacturer	Shenzhen Jian Feng Electronic Technology Co., Ltd.

Device Name	TENS & EMS Device
Model	FM-B2403
510(K) Number	K202866
Product Code	NUH, NGX
Panel Code	Physical Medicine, Neurology
Regulation Number	21 CFR 882.5890 21 CFR 890.5850
Regulation Class	Class II

5. Device Description / Design of Device

The device of the model FM-B2403A is a portable, battery powered (lithium battery 3.7V DC) multi-function device offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (EMS) qualities in one device, it can be used for arm, shoulder, neck, back, waist, abdomen, and leg.

4 channels that effectively transfer your desired choice of programmed electrical pulses directly through electrode adhesive pads to the suggested area of the body where the electrodes are placed, causing minimal muscle contractions. There are 24 modes of operations.

The electrode pads are cleared by FDA, and 510(k) number is K092546 for the electrode pads. They are used as an accessory to the TENS or EMS device unit, which transmits electrical current to patient skin. The electrical current is first transmitted via the lead wire or snap button then transmitted to the conductive gel which is adhered to patient skin. The electrode pads are composed of a cover, connector lead wire or snap button, conductive carbon film, conductive hydrogel, and an electrode carrier liner. It is non-sterile and intended for single adult patient (age≧18) multiple application use.

Its output waveform is provided 24 programs and 20 adjustable intensity levels. The LCD screen shows the information of program, level, operating time and channel.

6. Indication for Use

TENS:

The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities.

EMS:

The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.

7. Technological characteristics and substantial equivalence

7.1 The following table is the basic characteristic:

Table 1. FM-B2403A

Contents	New device	Predicate Device	SE
Trade Name	TENS & EMS Device	TENS & EMS Device	SE
Device Model	FM-B2403A	FM-B2403	/
510(k) Number	To Be Assigned	K202866	/
Manufacturer	Shenzhen Jian Feng Electronic Technology Co., Ltd.	Shenzhen Jian Feng Electronic Technology Co., Ltd.	SE
Regulatory Information	882.5890, 890.5850	882.5890, 890.5850	SE
Classification	Class II	Class II	SE
Product code	NUH, NGX	NUH, NGX	SE
Panel	Physical Medicine; Neurology	Physical Medicine; Neurology	SE
OTC/RX	OTC	OTC	SE
Intended Use	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities. EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities. EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.	SE
Apply parts of the body	Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom	Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom	SE
Power Source	Built-in 3.7V lithium battery	Built-in 3.7V lithium battery	SE
- Method of Line Current Isolation	BF	BF	SE
- Patient Leakage Current	/	/	
- Normal condition	<10μA	<10μA	SE
- Single fault condition	<50μA	<50μA	SE
Number of Output Modes	TENS:12, EMS:12	TENS:19, EMS:5	SE
Number of Output Channels	4	4	SE
Synchronous or alternating	Synchronous	Synchronous	SE
Method of Channel Isolation	By electrical circuit and software	By electrical circuit and software	SE
Regulated Current or Regulated Voltage	Regulated voltage control	Regulated voltage control	SE
Software/Firmware/Microprocessor Control?	Software	Software	SE

Automatic Overload Trip?		No	No	SE
Automatic No-Load Trip?		No	No	SE
Automatic Shut Off?		Yes	Yes	SE
Patient Override Control?		Yes	Yes	SE
Indicator Display	On/Off Status?	Yes	Yes	SE
	Low Battery?	Yes	Yes	SE
	Voltage/Current Level?	Yes	Yes	SE
Timer Range (minutes)		10~80	10~80	SE
Compliance with Voluntary Standards?		Yes. ANSI/AAMI/ES 60601-1 IEC60601-1-2 IEC 60601-2-10 IEC60601-1-11 ISO10993-5 ISO10993-10	Yes ANSI/AAMI/ES 60601-1 IEC60601-1-2 IEC 60601-2-10 IEC60601-1-11 ISO10993-5 ISO10993-10	SE
Accessories		Self-adhesive electrodes, electrode wires, adapter, USB cable	Self-adhesive electrodes, electrode wires, adapter, USB cable	SE
Compliance* with 21 CFR 898?		Yes	Yes	SE
Weight(g)		86g	82 g	SE, Note 1
Dimensions (mm) [D x W H]		110*61*24	110*60*15	
Housing Materials and Construction		ABS	ABS	SE
Biocompatibility		All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements	SE
Comparison in details: Note 1: The proposed device FM-B2403A has passed the IEC 60601-1 and AAMI / ANSI ES60601-1 test . The weight, dimensions, appearance of proposed device FM-B2403A has a little different from predicate device K202866, but these differences are insignificant and won't raise any new risk of safety and effectiveness..				

7.2 The following table is the output parameters:

Table 3 FM-B2403A

Contents	Proposed Device	Predicate Device	SE
Device Name, Model	FM-B2403A	FM-B2403	/
Waveform (e.g., pulsed monophasic, biphasic)	biphasic	biphasic	SE
Shape (e.g., rectangular, spike, rectified sinusoidal)	rectangular	rectangular	SE

Maximum Output Voltage (volts) (+/- 10%)	98@500Ω 150@2KΩ 165@10KΩ	97.6@500Ω 135@2KΩ 157@10KΩ	SE Note 1
Maximum Output Current (mA) (+/- 10%)	196@500Ω 75@2KΩ 16.5@10KΩ	195.2@500Ω 67.5@2KΩ 15.7@10KΩ	SE Note 1
Pulse Duration (μs)	50-180	90	SE, Note 1
Frequency† (Hz) [or Rate† (pps)]	<199	< 90.9	SE Note 1
Net Charge (micro coulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)	0.001@500Ω	0.001@500Ω	SE
Maximum Phase Charge, (μC)	35@500Ω	15.5@500Ω	SE Note 2
Maximum Current Density(mA/cm²)	0.5645@500Ω	0.1192@500Ω	SE Note 2
Maximum Power Density(mW/cm²)	0.003984@500Ω	0.176@500Ω	SE Note 2
Pulses per burst	2	2	SE
Bursts per second	1/50	1/30	SE Note 2
Burst duration (ms)	50	45	SE Note 2
Duty Cycle: Line (b) x Line (%)	7.2%	1.6%	SE Note 2
ON Time (seconds)	1	1	SE
OFF Time (seconds)	1	1	SE
Comparison: Note 1: There are some differences on the maximum output voltage ,maximum Output current, pulse duration, frequency between proposed device and predicate device K202866.All these parameters have passed IEC 60601-2-10 test codes. Therefore, these differences won't raise any new risk of safety and effectiveness. Note 2:There are some differences on the net charge, maximum current density ,maximum power density, bursts per second, burst duration and duty cycle between the proposed device and the predicate device K202866,but these parameters don't exceed the safety limit and have passed IEC 60601-2-10 test. The maximum average power density <0.25Watts/cm².Therefore, these differences won't raise any new safety and effectiveness risk.			

8. Non-clinical studies and tests performance:

Non-clinical tests have been conducted to verify that the transcutaneous electrical nerve stimulator and/or powered muscle stimulator meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

ANSI/AAMI/ES 60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

IEC60601-1-11, 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

IEC60601-2-10, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.

The body-contacting components of this device are electrode patches. We have directly purchased the electrode patches from qualified supplier which has obtained FDA clearance with a 510(k) number of K092546, so we have reason to believe that the electrode patches are safe for the users. The electrode patches comply to the following standards:

1) ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests for In Vitro Cytotoxicity;

2) ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

9. Clinical Performance Data

Not applicable.

10. Final conclusion:

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the model FM-B2403A is substantially equivalent to the predicate device K202866.