



March 3, 2022

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

Re: K213835

Trade/Device Name: TENS & EMS Device

Regulation Number: 21 CFR 882.5890; 21 CFR 890.5850

Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief;  
Powered muscle stimulator

Regulatory Class: Class II

Product Code: NUH, NGX

Dated: December 9, 2021

Received: December 9, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for 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

## Indications for Use

510(k) Number (if known)  
K213835

Device Name  
TENS & EMS Device

### 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  
[PRASStaff@fda.hhs.gov](mailto: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

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

Type of 510(k) submission: Traditional

Date of the summary prepared: Jan-30-2022

### 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, 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, China.

Contact Person: Feng Wen

Title: General Manager

Email: wenfeng@fzjhealth.com

Tel: +86-755-33858361 Fax: +86-755-33858360

### 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

### Subject Device Information

Trade Name: TENS & EMS Device

Common Name: TENS, EMS, Stimulator for pain relief;

Classification Name: Transcutaneous electrical nerve stimulator for pain relief;  
Powered muscle stimulator

Review Panel: Physical Medicine; Neurology

Product Code: NUH,NGX  
 Regulation Number: 21CFR882.5890, 21CFR890.5850  
 Device Classification: Class II  
 Use: Over-the-Counter Use (OTC)

#### Device Description / Design of Device

The device of the model TU3424-F 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  $\geq 18$ ) 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.

#### 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.

#### Technological characteristics and substantial equivalence

The following table is the basic characteristic:

Contents	New device	Predicate Device	SE
Trade Name	TENS & EMS Device	TENS & EMS Device	SE
Device Model	TU3424-F	FM-B2403	/
510(k) Number	K213835	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	<p>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.</p> <p>EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.</p>	<p>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.</p> <p>EMS: The device is designed to be used to stimulate healthy muscles in order to improve or facilitate muscle performance.</p>	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	<10 $\mu$ A	<10 $\mu$ A	SE
- Single fault condition	<50 $\mu$ A	<50 $\mu$ A	SE
Number of Output Modes	TENS:10, EMS:5	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	SE
	Low Battery?	Yes	SE
	Voltage/Current Level?	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)	110	82	SE, Note 1
Dimensions (mm) [D x W H]	161*60*16.5	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 TU3424-F has passed the IEC 60601-1 and AAMI / ANSI ES60601-1 test . The weight, dimensions, appearance of proposed device TU3424-F has a little different from predicate device K202866, but these differences are insignificant and won't raise any new risk of safety and effectiveness..			

The following table is the output parameters:

Contents	Proposed Device	Predicate Device	SE
Device Name, Model	TU3424-F	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%)	60@500Ω 95@2kΩ 153@10kΩ	97.6@500Ω 135@2KΩ 157@10KΩ	SE Note 1
Maximum Output Current (mA) (+/- 10%)	120@500Ω 47.5@2kΩ 15.3@10kΩ	195.2@500Ω 67.5@2KΩ 15.7@10KΩ	SE Note 1
Pulse Duration (μs)	50-300	90	SE, Note 1
Frequency† (Hz) [or Rate† (pps)]	<200 Hz	< 90.9	SE Note 1
Net Charge (micro coulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)	0.0001μC @500Ω	0.001@500Ω	SE
Maximum Phase Charge, (μC)	36@500Ω	15.5@500Ω	SE Note 2

Maximum Current Density(mA/cm <sup>2</sup> )	0.3456@500Ω	0.1192@500Ω	SE Note 2
Maximum Power Density(mW/cm <sup>2</sup> )	1.4930@500Ω	0.176@500Ω	SE Note 2
Pulses per burst	2	2	SE
Bursts per second	0.02	1/30	SE Note 2
Burst duration (ms)	50	45	SE Note 2
Duty Cycle: Line (b) x Line (%)	6.0	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/cm<sup>2</sup>,Therefore, these differences won't raise any new safety and effectiveness risk.

**Non-Clinical Tests Performed**

Compliance to applicable voluntary standards include: ANSI/AAMI/ES 60601-1, IEC60601-1-2, IEC 60601-2-10, IEC60601-1-11.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

**Final conclusion:**

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the model TU3424-F is substantially equivalent to the predicate device K202866 (Model: FM-B2403).