May 19, 2021

SHenzhen Jianfeng Electronic Technology Co., Ltd.
% Iris Lin
Account Manager
Intertek Testing Services Shenzhen Ltd. Guangzhou.
Block E, No.7-2 Guangdong Software Science Park, Caipin Road
Guangzhou Science City, GETDD, Guangdong 510700
China

Re: K202866
Trade/Device Name: TENS & EMS Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: February 24, 2021
Received: March 2, 2021

Dear Iris Lin:

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,

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

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)*

K202866

Device Name
TENS and 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.

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510(k) Summary

K202866

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: May-11-2021

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, China.

Contact Person: Feng Wen

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Application Correspondent

Company: SHENZHEN JIAN FENG ELECTRONIC TECHNOLOGY CO., LTD.

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Contact Person: Feng Wen

Title: General Manager

Email: wenfeng@fzjhealth.com

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

3. The Predicate Device Information

Basic Information	Predicate Device
Manufacturer	HIVOX BIOTEK INC.
Device Name and Model	HIVOX OTC Electrical Stimulator SEM44
510(k) Number	K171803
Product Code	NUH, NGX
Panel Code	Physical Medicine, Neurology
Regulation Number	21 CFR 882.5890 21 CFR 890.5850
Regulation Class	Class II

4. Subject Device Information

Trade Name: TENS & EMS Device

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: 21CFR882.5890, 21CFR890.5850
Device Classification: Class II
Use: Over-the-Counter Use (OTC)

5. Device Description / Design of Device

The subject device (Model: FM-B2403) 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:

Contents	Subject Device	Predicate Device	SE
Trade Name	TENS & EMS Device	HIVOX OTC Electrical Stimulator	SE
Device Model	FM-B2403	SEM44	/
510(k) Number	K202866	K171803	/
Manufacturer	Shenzhen Jian Feng Electronic Technology Co., Ltd.	HIVOX BIOTEK INC.	/

Regulatory Information	882.5890, 890.5850	1) 882.5890 2) 890.5850	/
Classification	Class II	Class II	/
Product code	NUH, NGX	NUH, NGX	/
Panel	Physical Medicine; Neurology	1) Neurology 2) Physical Medicine	/
OTC/RX	OTC	OTC	/
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 for stimulate healthy muscles in order to improve and 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	Batteries, 3x1.5V AAA	SE
Number of Output Modes	TENS:19, EMS:5	TENS: 15 EMS: 35	SE
Number of Output Channels	4	2	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?	Yes	Yes	SE
Automatic Overload Trip?	No	Yes	SE
Automatic No-Load Trip?	No	Yes	SE
Automatic Shut Off?	Yes	Yes	SE
Patient Override Control?	Yes	Yes	SE
Indicator Display? On/Off Status? Low Battery? Voltage/Current Level?	Yes	Yes	SE
Timer Range (minutes)	10-80	5-100	SE
Compliance with Voluntary Standards?	ANSI/AAMI/ES 60601-1 IEC60601-1-2 IEC 60601-2-10 IEC60601-1-11 ISO10993-5 ISO10993-10	IEC60601-1 IEC60601-1-2 IEC 60601-2-10 IEC60601-1-11 ISO10993-5 ISO10993-10	SE
Compliance* with 21 CFR 898?	Yes	Yes	SE
Weight(g)	82 g	89 g (including belt clip, without batteries), 123 g (including belt clip and batteries)	SE
Dimensions (mm) [D x W H]	110*60*15	132 x 63 x 29.5 mm (including belt clip)	SE
Housing Materials and Construction	ABS	ABS	SE

7.2The following table is the output parameters:

Contents	Subject Device	Predicate Device	Additional-Predicate Device	SE
Device Name, Model	FM-B2403	SEM44	JQ-5C	/
Waveform (e.g., pulsed monophasic, biphasic)	biphasic	biphasic	biphasic	SE
Shape (e.g., rectangular, spike, rectified sinusoidal)	Square	Square	Rectangular	SE
Maximum Output Voltage (volts) (+/- 10%)	97.6@500Ω 135@2KΩ 157@10KΩ	100volts peak-peak±10%@500Ω 180volts peak-peak±10%@2kΩ 250volts peak-peak±10%@10kΩ	62@500Ω	SE
Maximum Output Current (mA) (+/- 10%)	195.2@500Ω 67.5@2KΩ 15.7@10KΩ	200mA peak-peak±10% @500Ω 90mA peak-peak±10% @2kΩ 25mA peak-peak±10% @10kΩ	124@500Ω 37.6@2KΩ	SE
Pulse Duration (μsec)	90μS	50-450μS	100μS	SE
Frequency† (Hz) [or Rate† (pps)]	< 90.9Hz	1-150Hz	61Hz	SE
Net Charge (micro coulombs (μC) per pulse) (If zero, state method of achieving zero net charge.)	0.001@500Ω	0.001@500Ω	0	SE
Maximum Phase Charge, (μC)	15.5@500Ω	45@500Ω	17.92μC	SE
Maximum Current Density(mA/cm²)	0.1192@500Ω	0.667@500Ω	9.95 mA/cm²	SE
Maximum Power Density(mW/cm²)	0.176@500Ω	4.6@500Ω	2.7	SE
Pulses per burst	2	3	Not publicly available	SE
Bursts per second	1/30	2/60	Not publicly available	SE
Burst duration (ms)	45	36	Not publicly available	SE
Duty Cycle: Line (b) x Line (%)	0.016	36ms/390ms	Not publicly available	SE
ON Time (seconds)	1	2	Not publicly available	SE
OFF Time (seconds)	1	2	Not publicly available	SE
Standard/Guidance Document Referenced	ANSI/AAMI/ES 60601-1 IEC60601-1-2 IEC60601-1-11 IEC 60601-2-10 ISO 10993-5:2009 ISO 10993-10:2010	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO10993-5/10	Not publicly available	SE

8. 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.

9. Conclusion:
After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that the EMS and TENS Devices (Model FM-B2403) is substantially equivalent to the predicate device (Model: SEM44).