May 13, 2023

Hivox Biotek Inc.
Shaun Hsu
Regulatory Affairs Specialist
5F., No. 123, Xingde Rd.
Sanchong Dist.
New Taipei City, 24158
Taiwan

Re: K223308
Trade/Device Name: Heating Tens/ems, Ft-810r
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, IRT
Dated: January 17, 2023
Received: April 14, 2023

Dear Shaun Hsu:

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,

Pamela D. Scott -S

Pamela D. Scott
Assistant 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

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)*
K223308

Device Name
Heating TENS (FT-810R)

Indications for Use *(Describe)*
This home used device is designed to be used for adult and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. In addition, it also provides a heat function intended to temporarily relieve minor aches and pains.

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

1. Type of Submission Traditional

2. Date of Summary October 21, 2022

3. Submitter HIVOX BIOTEK INC.
Address: 5F., No. 123, Xingde Rd., Sanchong Dist.,
New Taipei City 24158, Taiwan, R.O.C.
Phone: +886-2-8511-2668
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Contact: Shaun Hsu (shaun.hsu@hivox-biotek.com)

4. Identification of the Subject Device

Proprietary Name:	Heating TENS
Model:	FT-810R
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NUH
Regulation Number:	21 CFR 882.5890
Device Class:	II

5. Identification of the Predicate Device #1

510(k) Number:	K203574
Manufacturer:	HIVOX BIOTEK INC.
Proprietary Name:	HIVOX OTC Electrical Stimulator
Model:	EM59-1
Regulatory Description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Power heating pad
Product Code:	NUH, IRT
Regulatory Number:	1) 21 CFR 882.5890 2) 21 CFR 890.5740
Device Class:	II

6. Identification of the Predicate Device #2

510(k) Number:	K211403
Manufacturer:	HIVOX BIOTEK INC.
Proprietary Name:	HIVOX OTC Electrical Stimulator
Model:	FT610-B
Regulatory Description:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NUH

Regulatory Number:	21 CFR 882.5890
Device Class:	II

7. Identification of the Reference Device

510(k) Number:	K163393
Manufacturer:	Hi-Dow International, Inc.
Proprietary Name:	Hi-Dow Wireless TENS/EMS
Model:	HD-5N
Regulatory Description:	Transcutaneous electrical nerve stimulator for pain relief
Product Code:	NUH, NGX
Regulatory Number:	21 CFR 882.5890
Device Class:	II

8. Device Description

The FT-810R with a remote controller is a self-adhesive TENS device with 15 adjustable intensity level for pain relief. Moreover, it also provides a heat function which can be used in conjunction with the TENS function. TENS, Transcutaneous Electrical Nerve Stimulation, refers to the electrical stimulation of nerves through the skin which is an effective non-pharmacological method of pain relief. It can be used for self-treatment. Any symptoms that could be relieved using TENS must be checked by your general practitioner who will also give you instruction on how to carry out a TENS self-treatment regime.

TENS device works by passing electrical currents over the skin via a set of gel pads. As a transfer medium, the gel pads are subject to natural wear and tear and must be replaced when they stop providing sufficient contact or the main device no longer sticks to the skin completely. Failure to replace the gel pad may lead to skin irritation as a result of heightened current density in particular areas.

9. Intended Use / Indications for Use of the Device

This home used device is designed to be used for adult and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. In addition, it also provides a heat function intended to temporarily relieve minor aches and pains.

10. Non-clinical Testing

A series of safety and performance tests, as follows, were conducted on the subject

device in accordance with FDA recognized consensus standards and/or guidance:

- Shelf life (ASTM F1980-16)
- Biocompatibility (ISO 10993-1 Edition 5.0, ISO 10993-5 Edition 3.0 and ISO 10993-10 Edition 3.0)
- Software validation (IEC 62304 Edition 1.1)
- Electromagnetic compatibility and electrical safety (ANSI/AAMI ES60601-1:2015/(R)2012, IEC 60601-1-2 Edition 4.0, IEC 60601-1-11 Edition 2.0 and IEC 60601-2-10 Edition 2.1)
- Function test (Guidance Document for Powered Muscle Stimulator 510(K)s. Document issued on: June 9, 1999)
- Usability test (IEC 60601-1-6 Edition 3.2 and IEC 62366-1 Edition 1.1)
- Function Validation (Attachment 19-1 Performance Verification Report)
- Output Waveform Validation (Guidance Document for Powered Muscle Stimulator 510(K)s. Document issued on: June 8, 1999, Attachment 19-3 Output Waveform Report)
- Impedance Validation (Attachment 19-4 Impedance Test Report)

All the test results demonstrate the subject device, Heating TENS (FT-810R), meets the requirements of its pre-defined acceptance criteria and intended use, and its substantially equivalent to the predicate device.

11. Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

12. Substantial Equivalence Comparison

The subject device, Heating TENS (FT-810R), was compared to the predicate devices and reference device in the table below:

Table 1 – Comparison to Predicate Devices and Reference Device

Comparison item	Subject device	Predicate device #1	Predicate device #2	Reference device	Substantial Equivalence Determination
510(k) Number	K223308	K203574	K211403	K163393	N/A
Device Name	Heating TENS	HIVOX OTC Electrical Stimulator	HIVOX OTC Electrical Stimulator	Hi-Dow Wireless TENS/EMS	
Model	FT-810R	EM59-1	FT610-B	HD-5N	
Manufacturer	HIVOX BIOTEK INC.	HIVOX BIOTEK INC.	HIVOX BIOTEK INC.	Hi-Dow International, Inc.	
Intended Use	This home used device is designed to be used for adult and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. In addition, it also provides a heat function intended to temporarily relief of minor aches and pains.	EM59-1: TENS: This function is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. SH: This function is designed to be used for temporary relief of minor aches and pains.	The FT610-B is designed for symptomatic relief and management of chronic pain, and for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities and lower extremities due to strain from exercise or normal household work activities.	TENS: To be used for the temporary relief of pain associated with sore or aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. EMS: It is intended for muscle conditioning, used for stimulating muscles including abdomen muscles in order to improve or facilitate muscle performance.	Subject device implements the same technological features as the predicate devices. We are using the FT610-B to show that FDA has cleared a TENS with heating capability for the same indication for use that we are seeking for the FT-810R that has maximum charge per phase of 7.2μ which is lower than the maximum charge per phase of the 810R. The primary predicate (predicate # 1) has a maximum charger per phase of 45μ and has a heating capability and an indication for use that is identical to which you are seeking for the 810R. Therefore, because the maximum charge per phase of the 810R falls between the charge per phase of the 610-B and the EM59-1 and the 810R has the same indication for use as the two predicates, The FT-810R is substantially equivalent to the legally marketed predicate. Additionally, reference device used for addition of wireless.
FDA Product Code	NUH	NUH, IRT	NUH	NUH, NGX	Identical to predicate device #2
Prescription or OTC	OTC	OTC	OTC	OTC	Identical
Power Source(s)	3.7 V Lithium-ion battery	Rechargeable battery	3.7 V Lithium-ion battery	DC 3.7V Lithium Battery	Identical
Function and Design	Electrical stimulation and heat	Electrical stimulation and heat	Electrical stimulation and heat	Electrical stimulation	Identical to predicate device
Heating setting	Low and high	Low and high	Nonadjustable	N/A	Predicate device #2 has nonadjustable heating setting which will stay continuously 43℃ unless user switch off the heating function. Hence, the setting differences would not raise concern in

Comparison item		Subject device	Predicate device #1	Predicate device #2	Reference device	Substantial Equivalence Determination
						safety or effectiveness from predicate device
Maximum Temperature Setting (℃)		43	43	43	N/A	Identical to predicate device
Output Pattern of the Heating		Delivers electrical stimulation and heat simultaneously	• Electrical stimulation only • Heat only • Electrical stimulation + Heat simultaneously	Delivers electrical stimulation and heat simultaneously	N/A	Identical to predicate device
Method of Line Current Isolation		N/A (internal power source)	N/A (internal power source)	N/A (internal power source)	Two separate devices, and use independent power supply system.	Identical to predicate device
Patient Leakage Current	Normal Condition (μA)	< 10	6.0	< 10	DC: <10 AC: <100	Identical to predicate device #2
	Single Fault Condition (μA)	< 50	5.6	< 50	DC: <50 AC: <500	Identical to predicate device #2
Number of Output Modes		4	TENS: 15 SH: 1	3	4	Mode differences would not raise concern in safety or effectiveness from predicate device
Number of output Channels	Synchronous or Alternating?	Single channel	2 Synchronous	Single channel	2 Channel Asynchronous	Identical to predicate device #2
	Method of Channel Isolation	N/A	By electrical circuit and software	N/A	Two separate devices, and use independent power supply system.	Identical to predicate device #2
Regulated Current or Regulated Voltage?		Current	Regulated current	Regulated current	Regulated Voltage	Identical to predicate device
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	Yes	Identical
Automatic Overload Trip?		Yes	Yes	Yes	No	Identical to predicate device
Automatic No-Load Trip?		Yes	Yes	Yes	No	Identical to predicate device
Automatic Shut Off?		Yes	Yes	Yes	Yes	Identical
Patient Override Control?		Yes	Yes	Yes	Yes	Identical
Indicator Display	On/Off Status?	Yes	Yes		Yes	Identical to predicate device #1
	Low Battery?	Yes	Yes		Yes	Identical to predicate device #1
	Voltage/ Current Level?	No	No		No	Identical to predicate device #1
Timer Range (minute)		20	5 to 100 minutes adjustable	20	45	Identical to predicate device #2
Compliant with Voluntary Standards?		ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1 / ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	Identical to predicate device #2

Comparison item		Subject device	Predicate device #1	Predicate device #2	Reference device	Substantial Equivalence Determination
		ISO 10993-5 ISO 10993-10 ISO 10993-23		ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	
Compliant with 21 CFR 898?		Yes	Yes	Yes	Yes	Identical
Weight (g)		102	Approx. 125 (including belt clip and battery)	47	Remote: 62 Receiver: 24	Weight differences would not raise concern in safety or effectiveness from predicate device
Dimensions (mm) [W × H × D]		300 × 100 × 15	Approx. 139 × 66 × 26 (including belt clip)	193 × 95 × 15	Remote: 108 × 53 × 15 Receiver: Φ57 × 12	Dimension differences would not raise concern in safety or effectiveness from predicate device
Housing Materials and Construction		PC/ABS plastic	Plastic (ABS) enclosure	PC/ABS plastic	ABS	Identical to predicate device
Waveform		Biphasic, Symmetrical	Biphasic	Biphasic, Symmetrical	Pulsed Biphasic	Identical to predicate device
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Identical
Maximum Output Voltage (Vp-p, ±10%)	@ 500 Ω	72	100	72	(TENS) MODE 3: 48.5V@500Ω (TENS) MODE 4: 41.1V@500Ω (EMS) MODE 1: 37.9V@500Ω (EMS) MODE 2: 46.8V@500Ω	No significant differences would raise concern in safety or effectiveness from predicate device
	@ 2 kΩ	112	180	112		
	@ 10 kΩ	120	250	120		
Maximum Output Current (mAp-p, ±10%)	@ 500 Ω	144	200	144	(TENS) MODE 3: 97mA@500Ω (TENS) MODE 4: 82.2mA@500Ω (EMS) MODE 1: 75.8mA@500Ω (EMS) MODE 2: 93.6mA@500Ω	No significant differences would raise concern in safety or effectiveness from predicate device
	@ 2 kΩ	56	90	56		
	@ 10 kΩ	12	25	12		
Pulse Width (μs)		200、400	50 to 450	100	(TENS) MODE 3: Continuous (TENS) MODE 4: 92.5 (EMS) MODE 1: 4.6 (EMS) MODE 2: 4.8	No significant differences would raise concern in safety or effectiveness from predicate device NOTE: Referring to “Maximum Phase Charge” for details
Frequency (Hz)		6~45	1 to 150	100	(TENS) MODE 3: 1.28 (TENS) MODE 4: 1~59.8 (EMS) MODE 1: 52.3 (EMS) MODE 2: 5.8	No significant differences would raise concern in safety or effectiveness from predicate device
For Interferential Modes Only: Beat Frequency (Hz)		N/A	N/A	N/A	N/A	Identical

Comparison item		Subject device	Predicate device #1	Predicate device #2	Reference device	Substantial Equivalence Determination
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A	YES	Identical to predicate device
	Phase Duration	N/A	N/A	N/A	TENS & EMS : 100μS	Identical to predicate device
Net Charge (μC per pulse @ 500Ω)		0	0	0	(TENS) MODE 3: 9.7μC@500Ω (TENS) MODE 4: 8.22μC@500Ω (EMS) MODE 1: 7.5μC@500Ω (EMS) MODE 2: 9.36μC@500Ω	Identical to predicate device
Maximum Phase Charge (μC @ 500Ω)		21.6	45	7.2	(TENS) MODE 3: 38.8μC@500Ω (TENS) MODE 4: 32.88μC@500Ω (EMS) MODE 1: 15μC@500Ω (EMS) MODE 2: 37.44μC@500Ω	Predicate device #1 was used to indicate that the Maximum Phase Charge of the subject device is much lower than Predicate device #1. The differences would not raise concern in safety or effectiveness from predicate device
Maximum Average Current (mA @ 500Ω)		9.04	13.5	10.182	(TENS) MODE 3: 0.0124mA@500Ω (TENS) MODE 4: 0.492mA@500Ω (EMS) MODE 1: 0.393mA@500Ω (EMS) MODE 2: 0.054mA@500Ω	No significant differences would raise concern in safety or effectiveness from predicate device
Electrode Conductive Surface Area (cm^2)		53.2	20.25	28	N/A	Electrode Conductive Surface Area of the subject device is larger than predicate devices. If subject device has the same Electrode Conductive Surface Area like the predicated devices which will result in a smaller current density and power density of the subject device compared to predicate devices #1 and #2, hence the differences would not raise concern in safety or effectiveness from predicate device
Maximum Current Density (mA/cm^2 @ 500Ω)		1.01	0.667	0.364	(TENS) MODE 3: 8.08mA/cm²@500Ω (TENS) MODE 4: 6.85mA/cm²@500Ω	No significant differences would raise concern in safety or effectiveness from predicate device

Comparison item	Subject device	Predicate device #1	Predicate device #2	Reference device	Substantial Equivalence Determination
				(EMS) MODE 1: 6.31mA/cm²@500Ω (EMS) MODE 2: 7.8mA/cm²@500Ω	Current density of the subject device is lower than 2mA/cm^2 which meets the requirement of IEC 60601-2-10.
Maximum Power Density (W/cm^2 @ 500Ω)	0.055	0.0046	0.00185	(TENS) MODE 3: 0.05W/cm2@ 500Ω (TENS) MODE 4: 1.68W/cm2@ 500Ω (EMS) MODE 1: 1.25W/cm2@ 500Ω (EMS) MODE 2: 0.21W/cm2@ 500Ω	No significant differences would raise concern in safety or effectiveness from predicate device Maximum Power Density < 0.25W/cm^2
Remote communication mode?	RF: 2.4GHz transceiver	N/A	N/A	RF: 2.4GHz transceiver	Identical to ref. device
Wireless	FCC Part 15 Conducted Emissions FCC Part 15 Radiated Emissions FCC ID : 2A32IRFM-001	N/A	N/A	FCC Part 15 Conducted Emissions FCC Part 15 Radiated Emissions Remote Control: FCC ID:2ACD4HD-5N-TX Device: FCC ID:2ACD4HD-5N-RX	Meets the same requirements as the reference device

13. Similarity and Difference

Based on the comparison information in our submission, the indications for use of the subject device is similar to the predicate devices as all three devices provide a TENS mode for relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities and lower extremities due to strain from exercise or normal household work activities. It also provides a heat function intended to temporarily relief minor aches and pains. The TENS and heat output parameters of the subject device is as safe and as effective as the predicate devices. The reference device is used to add wireless technology for remote control as all of the wireless specifications were based on the reference device.

14. Conclusion

After a series of non-clinical tests to ensure that our design outputs met the specified design inputs and needs of user, we believe that the subject device, Heating TENS (FT-810R), is substantially equivalent to the predicate device in safety and effectiveness.