March 10, 2021

Hivox Biotek Inc.
Ruby Lu
Regulatory Affairs Specialist
5F, No. 123, Xingde Road, Sanchong District,
New Taipei City, 241
Taiwan

Re: K203574
Trade/Device Name: HIVOX OTC Electrical Stimulator, EM59-l, HIVOX OTC Electrical Stimulator, EM59-2
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, IRT
Dated: November 30, 2020
Received: December 7, 2020

Dear Ruby Lu:

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 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)*
K203574

Device Name
HIVOX OTC Electrical Stimulator (EM59-1, EM59-2)

Indications for Use *(Describe)*
HIVOX OTC Electrical Stimulator, EM59-1
TENS: This function is designated 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.

HIVOX OTC Electrical Stimulator, EM59-2
TENS: This function is designated 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.
EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.
SH: This function is designed to be used for temporary relief of 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.

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

1. Type of Submission	Traditional
510(k) Number	K203574
2. Date of Summary	Mar. 2, 2021
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
Fax:	+886-2-8511-2669
Contact:	Ruby Lu (Ruby.Lu@hivox-biotek.com)

4. Identification of the Subject Device

510(k) number	K203574
Proprietary/Trade name:	HIVOX OTC Electrical Stimulator
Models:	EM59-1, EM59-2
Classification product code:	NUH
Subsequent product code:	NGX, IRT
Regulation number:	1) 882.5890 2) 890.5850 3) 890.5740
Regulation description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator 3) Power heating pad
Review panel:	1) Neurology 2) Physical Medicine 3) Physical Medicine
Device class:	II

5. Identification of the Predicate Device #1

510(k) number:	K162517
Proprietary/Trade name:	Electrical Pulse Stimulator
Models:	PL-029K13
Classification product code:	NUH, NGX, NYN, IRT
Regulation number:	882.5890

Regulation description:	Transcutaneous electrical nerve stimulator for pain relief
Review panel:	Neurology
Device class:	II

6. Identification of the Predicate Device #2

510(k) number:	K190347
Proprietary/Trade name:	HIVOX OTC Electrical Stimulator
Models:	EM49-1, EM49-2
Classification product code:	NUH
Subsequent product code:	NGX
Regulation number:	1) 882.5890 2) 890.5850
Regulation description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator
Review panel:	1) Neurology 2) Physical Medicine
Device class:	II

7. Intended Use / Indications for Use of the Device

HIVOX OTC Electrical Stimulator, EM59-1

TENS: This function is designated 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.

HIVOX OTC Electrical Stimulator, EM59-2

TENS: This function is designated 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.

EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.

SH: This function is designed to be used for temporary relief of minor aches and pains.

8. Device Description

HIVOX OTC Electrical Stimulators, EM59-1 and EM59-2, fall into the electrostimulation device category.

EM59-1 provides two basic functions, TENS and SH; EM59-2 provides three basic functions, TENS, EMS and SH:

(1) Electrical stimulation of nerve tracts (TENS)

(2) Electrical stimulation of muscle tissue (EMS)

(3) Superficial heat (SH)

Both two models feature two independent output channels and four self-adhesive electrode gel pads. They offer a wide range of functions for increasing general well-being, pain relief, maintaining physical fitness, relaxation, muscle revitalisation and combating tiredness. For these purpose, the user can either choose from pre-set programs or specify their own to suit the user's individual needs.

The size of the self-adhesive electrode gel pad is 45×45 mm supplied by Shaoxing DL Healthcare Co., Ltd. It is an OTC medical device cleared by FDA under K182111.

On the other hand, the electrode made by PET, sponge, PCB and protect cases is designed by HIVOX BIOTEK INC.

9. 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 4.0, 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 3.1 and IEC 62366-1 Edition 1.0)

All the test results demonstrate the subject device, HIVOX OTC Electrical Stimulator (EM59-1, EM59-2), meets the requirements of its pre-defined acceptance criteria and intended use, and its substantially equivalent to the predicate device.

10. Clinical Testing

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

11. Substantial Equivalence Comparison

The subject device, HIVOX OTC Electrical Stimulator (EM59-1, EM59-2), was compared to a predicate device and reference device respectively in the tables below:

Table 1 – Comparison to Predicate Device #1

Comparison item	Subject device		Predicate device #1
510(k) Number	K203574		K162517
Device Name	HIVOX OTC Electrical Stimulator		Electronic Pulse Stimulator
Model	EM59-1	EM59-2	PL-029K13
Manufacturer	HIVOX BIOTEK INC.		JKH Health Co., Ltd.
Intended Use	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. EM59-2: 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)		TENS Mode To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm and leg due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS Mode To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arm, abdomen, legs,

		and lower extremities (leg) due to strain from exercise or normal household work activities. EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. SH: This function is designed to be used for temporary relief of minor aches and pains.	and buttocks. Not intended for use in any therapy or for the treatment of any medical condition or disease. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating Mode Temporary relief of minor aches and pains.
Prescription or OTC		OTC	OTC
FDA Product Code		NUH, NGX, IRT	NUH, NGX, NYN, IRT
Power Source(s)		Rechargeable battery	Rechargeable battery
Function and Design		Electrical stimulation and heat	Electrical stimulation and heat
Heating Setting		Low and high	Low and high
Maximum Temperature Setting		43℃	43℃
Maximum Output Voltage (V_p, ±20%)	@ 500 Ω	50.0	46.0
	@ 2 kΩ	90.0	90.4
	@ 10 kΩ	125	124
Maximum Output Current (mA_p, ±20%)	@ 500 Ω	100	92.0
	@ 2 kΩ	45.0	45.2
	@ 10 kΩ	12.5	12.4
Pulse Period (μs)		50 to 450	5.6 to 806
Frequency (Hz)		1 to 150	1.24 to 178.5
Maximum Phase Charge (μC @ 500Ω)		45	16.9
Maximum Current Density (mA/cm^2 @ 500Ω)		0.667	3.29
Maximum Power Density		0.0046	0.00165

(W/cm^2 @ 500Ω)		
Output Patterns	● Electrical stimulation only ● Heat only ● Electrical stimulation + Heat simultaneously	● Electrical stimulation only ● Heat only ● Electrical stimulation + Heat simultaneously

Table 2 – Comparison to Predicate Device #2

Comparison item	**Subject device**		**Predicate device #2**	
510(k) Number	K203574		K190347	
Device Name	HIVOX OTC Electrical Stimulator		HIVOX OTC Electrical Stimulator	
Model	EM59-1	EM59-2	EM49-1	EM49-2
Manufacturer	HIVOX BIOTEK INC.		HIVOX BIOTEK INC.	
Intended use	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. EM59-2: TENS: This function is designed to be used for temporary relief of pain associated with sore and		EM49-1: TENS: This 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, lower extremities, abdomen and bottom due to strain from exercise or normal household work activities. EM49-2: TENS: This 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, lower extremities,	

		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: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. SH: This function is designed to be used for temporary relief of minor aches and pains.		abdomen and bottom due to strain from exercise or normal household work activities. EMS: This device is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.	
Prescription or OTC		OTC		OTC	
FDA product code		NUH, NGX, IRT		NUH, NGX	
Power Source(s)		Battery powered, d.c. 3.7 V, 1 × built-in rechargeable lithium-ion battery		Battery powered, d.c. 4.5 V, 3 × AAA batteries	
Method of Line Current Isolation		N/A (internal power source)		N/A (internal power source)	
Patient Leakage Current	Normal condition (μA)	6.0		6.0	
	Single fault condition (μA)	5.6		5.6	
Number of Output Modes		TENS: 15 SH: 1	TENS: 15 EMS: 35 SH: 1	TENS: 15	TENS: 15 EMS: 35

Number of output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	By electrical circuit and software	By electrical circuit and software
Regulated Current or Regulated Voltage?		Regulated current	Regulated current
Software/Firmware/Microprocessor Control?		Yes	Yes
Automatic Overload Trip?		Yes	Yes
Automatic No-Load Trip?		Yes	Yes
Automatic Shut Off?		Yes	Yes
Patient Override Control?		Yes	Yes
Indicator Display	On/Off Status?	Yes	Yes
	Low Battery?	Yes	Yes
	Voltage/Current Level?	Yes	Yes
Timer Range (minute)		5 to 100 minutes adjustable	5 to 100 minutes adjustable
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
Compliant with 21 CFR 898?		Yes	Yes
Weight (g)		Approx. 125 (including belt clip and battery)	Approx. 117 (including belt clip and batteries)
Dimensions (mm) [W × H × D]		Approx. 139 × 66 × 26 (including belt clip)	Approx. 132 × 63 × 29.5 (including belt clip)
Housing Materials and Construction		Plastic (ABS) enclosure	Plastic (ABS) enclosure
Waveform		Biphasic	Biphasic
Shape		Rectangular	Rectangular

Maximum Output Voltage (V_{p-p}, ±10%)	@ 500Ω	100	100
	@ 2 kΩ	180	180
	@ 10 kΩ	250	250
Maximum Output Current (mA_{p-p}, ±10%)	@ 500Ω	200	200
	@ 2 kΩ	90	90
	@ 10 kΩ	25	25
Pulse Width (μs)		50 to 450	50 to 450
Frequency (Hz)		1 to 150	1 to 150
For interferential modes only: - Beat Frequency (Hz)		N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A
	Phase Duration	N/A	N/A
Net Charge (μC per pulse @ 500Ω)		0	0
Maximum Phase Charge (μC @ 500Ω)		45	45
Maximum Average Current (mA @ 500Ω)		13.5	13.5
Electrode Conductive Surface Area (cm^2)		20.25	20.25
Maximum Current Density (mA/cm^2 @ 500Ω)		0.667	0.667
Maximum Power Density (W/cm^2 @ 500Ω)		0.0046	0.0046
Output Intensity		TENS: Level 0 to 50 EMS: Level 0 to 50 SH: Level LOW and HI	TENS: Level 0 to 50 EMS: Level 0 to 50
Heating Level (°C)		Level LOW: up to 41 Level HI: up to 43	N/A
Operating Condition		Temperature: 5°C to 40°C Humidity: 15% RH to 90% RH	Temperature: 5°C to 40°C Humidity: 15% RH to 90% RH
Storage Condition		Temperature: 0°C to 40°C	Temperature: 0°C to 40°C

	Humidity: 0% RH to 90% RH	Humidity: 0% RH to 90% RH
Use Altitude Limit (m)	3000	3000
Use Atmospheric Pressure (hPa)	700 to 1060	700 to 1060

12. Similarity and Difference

Based on the comparison information in our submission, we can determine that the subject devices almost identical to the predicate devices #2 in all aspect, except it add a SH function. On the other hand, the subject devices have the same intended use and provide the same functions by the same operating principle as the predicate device #1, except the predicate device #1 includes an additional intended use for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. Although there are still several specifications different between the subject devices and predicate devices, the subject devices have undergone and passed a series of safety tests complied with the specific FDA-recognized consensus standards to demonstrate these differences would not adversely impact the safety and effectiveness of the subject device. Therefore, the differences between the subject devices and the predicate devices would not raise any problem in substantial equivalence claims.

13. Conclusion

After analyzing a series of non-clinical test results we have ensure that all of our design outputs meet the specified requirements of inputs, and also the final product meets the user needs. Thus, we can reasonably believe that the subject device, HIVOX OTC Electrical Stimulator (EM59-1, EM59-2), is substantially equivalent to the predicate devices in safety and effectiveness.