October 15, 2021

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

Re: K211403
Trade/Device Name: HIVOX OTC Electrical Stimulator, FT610-B
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 16, 2021
Received: July 19, 2021

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,

For
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)*
K211403

Device Name
HIVOX OTC Electrical Stimulator (FT610-B)

Indications for Use *(Describe)*
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. It is also indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication. 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 15, 2021

3. Submitter

HIVOX BIOTEK INC.
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Phone: +886-2-8511-2668
Fax: +886-2-8511-2669
Contact: Ruby Lu
(Ruby.Lu@hivox-biotek.com)

4. Identification of the Subject Device

Proprietary Name: HIVOX OTC Electrical Stimulator
Model: FT610-B
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: K162517
Manufacturer: JKH Health Co., Ltd.
Proprietary Name: Electronic Pulse Stimulator
Model: PL-029K13
Regulatory Description: Transcutaneous electrical nerve stimulator for pain relief
Product Code: NUH, NGX, NYN, IRT
Regulatory Number: 21 CFR 882.5890
Device Class: II

6. Identification of the Reference Device

510(k) Number: K183110
Manufacturer: LifeCare Ltd.
Proprietary Name: LIVIA
Regulatory Description: Transcutaneous electrical nerve stimulator for pain relief
Product Code: NUH
Regulatory Number: 21 CFR 882.5890

Device Class: II

7. Device Description

The subject device is a self-adhesive TENS device with 15 adjustable intensity levels for pain relief. Moreover, it also provides a heat function which can be used alone, or in conjunction with the TENS function simultaneously. TENS, Transcutaneous Electrical Nerve Stimulation, refers to the electrical stimulation of nerves through the skin which is an effective 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 unit 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.

This device is only compatible with the 50 mm x 56 mm gel pads which are the OTC medical device cleared by FDA under K132588, and come with the device.

8. Intended Use / Indications for Use of the Device

The subject device 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. It is also indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication. In addition, it also provides a heat function intended to temporarily relieve minor aches and pains.

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 (FT610-B), 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 (FT610-B), was compared to the predicate and reference devices in the tables below:

Comparison item	Subject device	Primary Predicate	Reference Device	Substantial Equivalence Determination
510(k) Number	To be assigned	K162517	K183110	N/A
Device Name	HIVOX OTC Electrical Stimulator	Electronic Pulse Stimulator	LIVIA	
Model	FT610-B	PL-029K13		
Manufacturer	HIVOX BIOTEK INC.	JKH Health Co., Ltd	LifeCare Ltd.	
Intended use	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. It is also	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	The Livia 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 (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. The Livia is	Subject device has the same technological features as the primary predicate (TENS + heating) excluding PMS. Subject device combines the heat output parameter on primary predicate device and the stimulation output

	indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication. In addition, it also provides a heat function intended for temporary relief of minor aches and pains.	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 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.	also indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.	parameter on reference device, which contain the indication for use on dysmenorrhea.
FDA Product Code	NUH	NUH, NGX, NYN, IRT	NUH	Identical to reference device
Prescription or OTC	OTC	OTC	OTC	Identical to primary predicate and reference

					device
Power Source(s)		Rechargeable battery	Rechargeable battery	Rechargeable battery	Identical to primary predicate device and reference device
Function and Design		Electrical stimulation and heat	Electrical stimulation and heat	Electrical stimulation	Identical to primary predicate device
Heating setting		Nonadjustable	Low and high	N/A	No different in safety or effectiveness from primary predicate device
Maximum Temperature Setting (℃)		43	43	N/A	Identical to primary predicate device
Output Pattern of the Heating		Delivers electrical stimulation and heat simultaneously	Delivers electrical stimulation and heat simultaneously	N/A	Identical to primary predicate device
Maximum Output Voltage (V_{p-p})	@ 500 Ω	72 ±10%	Mode 1: This mode cycles the following modes Mode 2: 31.2 ±20% Mode 3: 46.0 ±20% Mode 4: 42.0 ±20% Mode 5: 27.6 ±20% Mode 6: 27.6 ±20% Mode 7: 40.8 ±20% Mode 8: 23.2 ±20%	65.6 ±10%	No different in safety or effectiveness from reference device
	@ 2 kΩ	112 ±10%	Mode 1: This mode cycles the following modes Mode 2: 68.0 ±20% Mode 3: 90.4 ±20% Mode 4: 68.8 ±20% Mode 5: 60.0 ±20%	115 ±10%	

			Mode 6: 60.0 ±20% Mode 7: 84.0 ±20% Mode 8: 50.4 ±20%		
	@ 10 kΩ	120 ±10%	Mode 1: This mode cycles the following modes Mode 2: 118 ±20% Mode 3: 124 ±20% Mode 4: 78.4 ±20% Mode 5: 115 ±20% Mode 6: 115 ±20% Mode 7: 124 ±20% Mode 8: 99.2 ±20%	121 ±10%	
Maximum Output Current (mA_{p-p})	@ 500 Ω	144 ±10%	Mode 1: This mode cycles the following modes Mode 2: 62.4 ±20% Mode 3: 92.0 ±20% Mode 4: 84.0 ±20% Mode 5: 55.2 ±20% Mode 6: 55.2 ±20% Mode 7: 81.6 ±20% Mode 8: 46.4 ±20%	130.4 ±10%	
	@ 2 kΩ	56 ±10%	Mode 1: This mode cycles the following modes Mode 2: 34.0 ±20% Mode 3: 45.2 ±20% Mode 4: 34.4 ±20% Mode 5: 30.0 ±20% Mode 6: 30.0 ±20% Mode 7: 42.0 ±20% Mode 8: 25.2 ±20%	57.5 ±10%	
	@ 10 kΩ	12 ±10%	Mode 1: This mode cycles the following modes Mode 2: 11.8 ±20%	12.1 ±10%	

			Mode 3: 12.4 ±20% Mode 4: 7.84 ±20% Mode 5: 11.5 ±20% Mode 6: 11.5 ±20% Mode 7: 12.4 ±20% Mode 8: 9.92 ±20%		
Pulse Width (μs)		100	5.6~806	100	Identical to reference device
Frequency (Hz)		100	Mode 1: This mode cycles the following modes Mode 2: 73.5 Mode 3: 13.7~59.5 Mode 4: 1.24 Mode 5: 104.1 Mode 6: 104.1 Mode 7: 20.8 Mode 8: 178.5	100	Identical to reference device
Maximum Phase Charge (μC @ 500Ω)		7.2	Mode 1: This mode cycles the following modes Mode 2: 11.5 Mode 3: 16.9 Mode 4: 15.5 Mode 5: 10.2 Mode 6: 10.2 Mode 7: 15.0 Mode 8: 8.54	6.56	No different in safety or effectiveness from reference device
Maximum Current Density (mA/cm^2 @ 500Ω)		0.364	Mode 1: This mode cycles the following modes Mode 2: 2.23 Mode 3: 3.29 Mode 4: 3.00 Mode 5: 1.97 Mode 6: 1.97	0.492	

		Mode 7: 2.91 Mode 8: 1.66		
Maximum Power Density (W/cm^2 @ 500Ω)	0.00185	Mode 1: This mode cycles the following modes Mode 2: 0.94 Mode 3: 0.38~1.65 Mode 4: 0.03 Mode 5: 1.04 Mode 6: 1.04 Mode 7: 0.46 Mode 8: 1.26	0.00228	

12. Similarity and Difference

Based on the comparison information in our submission, both subject device and primary predicate device have the same indication for use on TENS mode and heat mode, which relieve the 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, and temporarily relieve the minor aches and pain. Primary predicate device has more indication for use on PMS mode, but subject device does not have a PMS mode.

Besides, the subject device added an indication for use on temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication as all of the TENS stimulation output parameters were based on reference device.

There is no difference in safety or effectiveness of the heat output parameters between subject device and primary predicate device. There is no difference in safety or effectiveness of TENS output parameters between subject device and reference device.

13. Conclusion

After a series of non-clinical tests to ensure our design outputs met the specified design inputs and needs of the user, we believe that the subject device, HIVOX OTC Electrical Stimulator (FT610-B), is substantially equivalent to the predicate device in safety and effectiveness.