March 15, 2019

Hivox Biotek Inc.
Marx Lee
Regulatory Affairs
5F., No. 123, Xingde Rd.
Sanchong Dist.
New Taipei City, TW 24158

Re: K190347
Trade/Device Name: HIVOX OTC Electrical Stimulator
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 13, 2019
Received: February 14, 2019

Dear Marx Lee:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190347

Device Name
HIVOX OTC Electrical Stimulator (EM49-1, EM49-2)

Indications for Use *(Describe)*
HIVOX OTC Electrical Stimulator, EM49-1 –
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.

HIVOX OTC Electrical Stimulator, EM49-2 –
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.

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.

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"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

6.1 Type of Submission: Special

6.2 Date of Summary: February 13, 2019

6.3 Submitter:

Address:	HIVOX BIOTEK INC. 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:	Marx Lee (marx.lee@hivox-biotek.com)

6.4 Identification of the Device:

Proprietary/Trade name:	HIVOX OTC Electrical Stimulator
Model Number:	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

6.5 Identification of the Predicate Device:

Predicate Device Name:	HIVOX OTC Electrical Stimulator
Model Number:	SEM44, SEM44-1
Manufacturer:	HIVOX BIOTEK INC.

Classification Product Code:	NUH
Subsequent Product Code:	NGX
Regulation number:	1) 882.5890
	2) 890.5850
Device Class:	II
510(k) Number:	K171803

6.6 Intended Use/ Indications for Use of the Device

HIVOX OTC Electrical Stimulator, EM49-1 –

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.

HIVOX OTC Electrical Stimulator, EM49-2 –

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.

6.7 Device Description

HIVOX OTC Electrical Stimulator – EM49-1 and EM49-2, falls into the electro stimulation device category.

EM49-1 provides one basic function, TENS, whereas EM49-2 provides two basic functions, TENS/EMS:

1. Electrical stimulation of nerve tracts (TENS)
2. Electrical stimulation of muscle tissue (EMS)

The two models also feature two independent stimulation channels and four adhesive electrodes which FDA cleared k number is K132588. For TENS, EM49-1 and EM49-2 are 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; for EMS, EM49-2 is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. For these purposes, the user can either choose from pre-set programs or specify their own to suit the user's individual needs.

The principle of electro stimulation units is based on the imitation of impulses in our bodies that are transferred to nerve and muscle fibers with electrodes via our skin. The electrodes can be applied to many parts of the body. In certain applications the user will merely notice a slight tingling or vibrating sensation. For EM49-1, the electrical impulses that are sent into the tissue influence the transmission of stimulation into nerves and nerve centers in the application area; for EM49-2, the electrical impulses that are sent into the tissue influence the transmission of stimulation into nerves, nerve centers and muscle groups in the application area.

6.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, HIVOX OTC Electrical Stimulator (EM49-1, EM49-2).

- Shelf Life
- Biocompatibility
- Software Validation
- Electromagnetic compatibility and electrical safety
- Function test
- Usability

All the test results demonstrate HIVOX OTC Electrical Stimulator (EM49-1, EM49-2) meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

6.9 Clinical Testing

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

6.10 Comparison of Differences and Substantial Equivalence Determination

The HIVOX OTC Electrical Stimulator (EM49-1, EM49-2) submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared HIVOX OTC Electrical Stimulator (SEM44, SEM44-1) (K171803). Differences between the devices cited in the following do not raise any new issue of substantial equivalence.

Subject device	Predicate device	Substantial equivalence determination
Model: EM49-1/EM49-2	Model: SEM44/SEM44-1	Different in product model. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Negative display type LCD	Positive display type LCD	Changed for the sake of product segmentation. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Arrangement of buttons		Changed for the sake of product segmentation. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Type of connection cable plug		Changed for the sake of product segmentation. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
PCB layout		Changed due to the use of different type of LCD and arrangement of buttons. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.
Weight		Difference because of different design of product appearance. However, it does not affect the intended use or alter the fundamental scientific technology of subject device.

6.11 Discussion

The HIVOX OTC Electrical Stimulator (EM49-1, EM49-2) has been compared with "HIVOX OTC Electrical Stimulator (SEM44, SEM44-1)". The subject device has same intended use, principle of operation and technological characteristics as the predicate device. We have completed the design control process and the validation tests to confirm the safety and performance of subject device. Although there are some specifications that are different between two devices, the test results complied with the test requests, and this demonstrates that the differences between these parameters would not impact the safety and effectiveness of the subject device. Therefore, the difference between the subject device and the predicate device did not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, safety and performance claims.

6.12 Conclusion

After analyzing non-clinical laboratory studies and related testing data, it can be concluded that the HIVOX OTC Electrical Stimulator (EM49-1, EM49-2) is substantially equivalent to the predicate device.