October 5, 2023

Hivox Biotek Inc.
Leslie Peng
Senior Product Manager
5F., No. 123, Xingde Rd., Sanchong Dist.
New Taipei City, 24158
Taiwan

Re: K232675
Trade/Device Name: Heating Tens, FT-615
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: September 1, 2023
Received: September 1, 2023

Dear Leslie Peng:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert Kang -S

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K232675

Device Name
HEATING TENS, FT-615

Indications for Use *(Describe)*
The FT-615 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 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.

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510(k) SUMMARY

1. Type of Submission Special

2. Date of Summary 01.09, 2023

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: Leslie Peng
(leslie.peng@hivox-biotek.com)

4. Identification of the Subject Device

Proprietary/Trade name:	HEATING TENS
Models:	FT-615
Classification product code:	NUH
Regulation number:	882.5890
Regulation description:	Transcutaneous electrical nerve stimulator for pain relief
Review panel:	Neurology
Device class:	II

5. Identification of the Predicate Device

510(k) number:	K211403
Proprietary/Trade name:	HIVOX OTC Electrical Stimulator
Models:	FT610-B
Classification product code:	NUH
Regulation number:	882.5890
Regulation description:	Transcutaneous electrical nerve stimulator for pain relief
Review panel:	Neurology
Device class:	II

6. 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.

7. 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 relief of minor aches and pains.

8. 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, HEATING TENS (FT-615), meets the requirements of its pre-defined acceptance criteria and intended use, and its substantially equivalent to the predicate device.

9. Clinical Testing

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

10. Comparison of Differences and Substantial Equivalence Determination

The subject device, HEATING TENS (FT-615), submitted in this 510(k) file is substantially equivalent in intended use, design, functions, technology, operation principles, materials, PCBA, software, electrode area and performance to the cleared HIVOX OTC Electrical Stimulator (FT610-B)(K211403). Differences between the devices cited in the following do not raise any new issue of substantial equivalence.

<table>
<tr><th>Subject device</th><th>Predicate device</th><th>Substantial Equivalence Determination</th></tr>
<tr><td>K232675</td><td>K211403</td><td rowspan="3">N/A</td></tr>
<tr><td>HEATING TENS</td><td>HIVOX OTC Electrical Stimulator</td></tr>
<tr><td>FT-615</td><td>FT610-B</td></tr>
<tr><td colspan="2">Housing</td><td>The housing is different but all of them material are same. It does not affect the intended use, biocompatibility or alter the fundamental scientific technology of subject device.</td></tr>
<tr><td colspan="2">Dimensions</td><td>Slight different in device dimensions because the design of product appearance. However, it does not affect the usability of the device.</td></tr>
</table>

11. Discussion

Based on the comparison information in our submission, we can determine that the subject device is similar to the predicate device in most aspect. The subject device has the same intended use, provided the same functions by the same operating principle as the predicate device, except housing and dimensions. The subject device has same material, design, technology, PCBA, software, electrode area and performance to

demonstrate these differences would not adversely impact the safety and effectiveness of the subject devices. The differences between the subject devices and the predicate device would not raise any problem in substantial equivalence claims.

12. 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 devices, HEATING TENS (FT-615), is substantially equivalent to the predicate device in safety and effectiveness.