December 17, 2024

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

Re: K242815
Trade/Device Name: Pocket Tens (EP-300)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: September 6, 2024
Received: September 18, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242815

Device Name

POCKET TENS (EP-300)

Indications for Use *(Describe)*

POCKET TENS (EP-300) which is home used device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

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.

510(k) SUMMARY

1. **Type of Submission** Traditional

2. **Date of Summary** December 16, 2024

3. **Submitter** HIVOX BIOTEK INC.

Address:	5F., No. 123, Xingde Rd., Sanchong District, New Taipei City 241, Taiwan, R.O.C.
Phone:	+886-2-8511-2668
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Contact:	Leslie Peng (leslie.peng@hivox-biotek.com)

4. **Identification of the Subject Device**

Proprietary name:	POCKET TENS
Model:	EP-300
Regulation number:	21 CFR 882.5890
Regulation description:	Transcutaneous electrical nerve stimulator for pain relief
Product code:	NUH
Device class:	II

5. **Identification of the Predicate Device #1**

510(k) number:	K171803
Manufacturer:	HIVOX BIOTEK INC.
Proprietary name:	HIVOX OTC Electrical Stimulator
Model:	SEM44-1
Primary Regulation number:	21 CFR 882.5890
Primary Regulation description:	Transcutaneous electrical nerve stimulator for pain relief
Product code:	NUH, NGX
Device class:	II

6. Identification of the Predicate Device #2

510(k) number:	K140650
Manufacturer:	HIVOX BIOTEK INC.
Proprietary name:	HIVOX Electric Stimulator OTC TENS, Rapid Relief™ Pennypad PP-904
Model:	PP-904
Regulation number:	21 CFR 882.5890
Regulation description:	Transcutaneous electrical nerve stimulator for pain relief
Product code:	NUH
Device class:	II

7. Device Description

This device powered by CR2032 Lithium 3V battery is a self-adhesive TENS with 15 adjustable intensity levels falling into the electro-stimulation device category. It includes pocket storage rack for electrodes and TENS device. It designed for shoulder, back, upper extremities (arm) and lower extremities (leg) pain relief. Users only need to place the electrode gel pads on the sides of pain point and then power on the device, and adjust the pulse intensity to a proper level to start a 20 minute treatment session. For optimum result, rest 30 minutes between sessions.

TENS refers to the electrical stimulation of nerves through the skin which is a non-pharmacological method of pain relief. Any symptoms that could be relieved using TENS must be checked by patient's general practitioner who will also give patient instruction on how to carry out a TENS self-treatment regime.

This device is only compatible with the 75 mm x 48 mm gel pads which are the OTC medical device cleared by FDA under K083302 or K180865, and come with the device.

8. Intended Use / Indications for Use

POCKET TENS (EP-300) which is home used device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

9. Substantial Equivalence Comparison

Refer to section 12 for complete comparison table.

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
- Gel pad lifetime
- Biocompatibility
  - Biological evaluation (ISO 10993-1:2018)
  - In Vitro Cytotoxicity Test (ISO 10993-5:2009)
  - Skin Sensitization Study (ISO 10993-10:2021, ISO 10993-10:2010)
  - Skin Irritation Study (ISO 10993-23:2021, ISO 10993-10:2010)
- Software validation
  - IEC 62304:2006+A1:2015
  - ISO 14971:2019
  - ISO TR 24971:2020
- EMC and electrical safety
  - IEC 60601-1-2:2014+A1:2020
  - IEC TR 60601-4-2:2016
  - ANSI/AAMI ES60601-1:2005+A2:2021
  - IEC 60601-1-11:2015+A1:2020
  - IEC 60601-2-10:2012+A1:2016
  - IEC 60086-4:2019
- Performance verification
  - Guidance Document for Powered Muscle Stimulator 510(K)s. (June 9, 1999)
- Output waveform validation
- Impedance validation
- Usability
  - IEC 60601-1-6:2010+A2:2020
  - ANSI/AAMI/IEC 62366-1:2015+A1:2020

All the test results demonstrate the subject device, POCKET TENS (EP-300), meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate devices.

11. Clinical Testing

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

12. Substantial Equivalence Comparison

The subject device, POCKET TENS (EP-300), was compared to the predicate devices in the table below:

Comparison item	Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
510(k) number	K242815	K171803	K140650	N/A
Device name	POCKET TENS	HIVOX OTC Electrical Stimulator	HIVOX Electric Stimulator OTC TENS, Rapid Relief™ Pennypad PP-904	
Model	EP-300	SEM44-1	PP-904	
Manufacturer	HIVOX BIOTEK INC.	HIVOX BIOTEK INC.	HIVOX BIOTEK INC.	
Intended Use	POCKET TENS (EP-300) which is home used device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work	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.	The HIVOX Electric Stimulator OTC TENS, Rapid Relief ™ Pennypad PP-904, is indicated for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg), and lower back due to strain from exercise or normal household and work activities.	The subject device and two predicate devices are designed to be used for temporary relief of pain associated with sore, aching muscle. The application area of the subject device (shoulder, back, upper extremities (arm) and lower extremities (leg)) is within the scope of the **Predicate device #1.**

Comparison item		Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
		activities.			
FDA product code		NUH	NUH, NGX	NUH	All predicates have NUH product code
Prescription or OTC		OTC	OTC	OTC	Identical to predicate devices
Basic unit characteristics					
Power source(s)		CR2032 Lithium 3V	4.5V (batteries, 3x1.5V AAA)	CR2032 Lithium 3V	Identical to **Predicate device #2**
Function and design		Electrical stimulation	Electrical stimulation	Electrical stimulation	Identical to predicate devices
Number of output modes		TENS:1	TENS:15	TENS:1	Identical to **Predicate device #2**
Number of output channels	Synchronous or Alternating?	Single Channel	Two Channels (Synchronous)	Single Channel	Identical to **Predicate device #2**
	Method of channel isolation	N/A	By electrical circuit and software	N/A	Identical to **Predicate device #2**
Regulated current or regulated voltage?		Regulated voltage	Regulated voltage	Regulated voltage	Identical to predicate devices
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Identical to predicate devices
Automatic overload trip?		Yes	Yes	Yes	Identical to predicate devices
Automatic no-load trip?		Yes	Yes	Yes	Identical to predicate devices

Comparison item		Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
Automatic shut off?		Yes	Yes	Yes	Identical to predicate devices
Patient override control?		Yes	Yes	Yes	Identical to predicate devices
Indicator display	On/off status?	No	Yes	No	Identical to **Predicate device #2**
	Low battery?	No	Yes	No	Identical to **Predicate device #2**
	Voltage/ current level?	No	Yes	No	Identical to **Predicate device #2**
Timer range (minutes)		20	5-100	20	Identical to **Predicate device #2**

Comparison item	Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
Compliance with voluntary standards?	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-10:2021 ISO 10993-23:2021 IEC 62304:2006+A1:2015 ISO 14971:2019 ISO TR 24971:2020 IEC 60601-1-2:2014 +A1:2020 IEC TR 60601-4-2:2016 ANSI/AAMI ES60601-1: 2005+A2:2021 IEC 60601-1-11:2015 +A1:2020 IEC 60601-2-10:2012 +A1:2016 IEC 60086-4:2019 IEC 60601-1-6:2010 +A2:2020 ANSI/AAMI/IEC 62366-1: 2015+A1:2020	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 ISO 10993-5/10	IEC/EN 60601-1 IEC/EN 60601-1-2 IEC/EN 60601-2-10	The subject device complies with the latest standards.
Compliance with 21 CFR	Yes	Yes	Yes	Identical to predicate devices

Comparison item		Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
898?					
Weight		Main device (including a set of pad): 35.6 g Gel pads (2 pieces): 9.4 g Battery: 3.0 g	89 g (including belt clip, without batteries), 123 g (including belt clip and batteries)	13.7 g (excluded battery)	The differences from weight would not raise concern in safety or effectiveness as predicate devices
Dimensions [W × H × D]		Approx. Main device: 66.8 × 35.0 × 10.6 mm Pad: 99.5 × 62.0 × 1.0 mm Wire: 391.0 mm	Approx. 132 × 63 × 29.5 mm (including belt clip)	Approx. 113 × 70 × 10 mm	The differences from dimension would not raise concern in safety or effectiveness as predicate devices
Housing materials and construction		ABS plastic enclosure	ABS Plastic enclosure	ABS Plastic enclosure	Identical to predicate devices
Output specifications					
Waveform		Biphasic, Symmetrical	Biphasic, Symmetrical	Monophasic with reversing polarity each phase	Identical to **Predicate device #1**
Shape		Rectangular	Rectangular	Rectangular	Identical to predicate devices
Maximum output	@ 500 Ω	50V for both phases, peak of 25V for each phase	100V peak-to-peak, 50V peak for each phase	30V peak monophasic	Refer to Section 13 for substantial equivalence

Comparison item		Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
voltage (Vp-p, ±10%)	@ 2 kΩ	92	180	89.6	
	@ 10 kΩ	101	250	96	
Maximum output current (mAp-p, ±10%)	@ 500 Ω	100mA peak-to-peak, 50mA peak	200	60mA peak	Refer to Section 13 for substantial equivalence
	@ 2 kΩ	37.5	90	44.8	
	@ 10 kΩ	10.1	25	9.6	
Pulse Width (μs)		50mA x 0.4mSec = 20 μC	50-450	200	Refer to Section 13 for substantial equivalence
Frequency (Hz)		4, 6 and 50	1-150	2, 5 and 40	Refer to Section 13 for substantial equivalence
Net charge (μC per pulse @ 500Ω)		0	0.001	0.2304	Refer to Section 13 for substantial equivalence
Maximum phase charge (μC @ 500Ω)		20	0.045 = 45 μC	60mA x 0.2mSec = 12 μC	Refer to Section 13 for substantial equivalence
Maximum average current (mA @ 500Ω)		3.46	13.5	2.303	Refer to Section 13 for substantial equivalence
Electrode conductive surface area (cm^2)		31.04 cm^2×2 (=62.08 cm^2)	20.25 cm^2×4 (=81cm^2)	20.366cm^2×2 (=40.732 cm^2)	Refer to Section 13 for substantial equivalence

Comparison item		Subject device	Predicate device #1	Predicate device #2	Substantial Equivalence Determination
Maximum current density (mA/cm^2 @ 500Ω)		1.61080	0.667	2.828	Refer to Section 13 for substantial equivalence
Maximum power density (W/cm^2 @ 500Ω)		0.0801	0.0046	0.163	Refer to Section 13 for substantial equivalence
Burst Mode	Pulse per burst	N/A	3	N/A	Identical to **Predicate device #2**
	Burst per second	N/A	2/60Hz	N/A	
	Burst duration	N/A	36ms	N/A	
	Duty cycle	N/A	36/390ms	N/A	
Average DC current through electrodes when device is on but no pulses are being applied (μA)		0	0	N/A	Identical to **Predicate device #1**

13. Similarity and Difference

The subject device and two predicate devices are designed to be used for temporary relief of pain associated with sore, aching muscle. They all fall into the electrical stimulation device category. The application area of the subject device (shoulder, back, upper extremities (arm) and lower extremities (leg)) is within the scope of the predicate device #1 (K171803). Therefore, it acts as the primary predicate device.

The predicate device #2 (K140650) is used to support the demonstration on some technical characteristics and specifications. Although the subject device has slightly different indications for use in comparison to the predicate device #2, the differences do not constitute a new intended use. They still fall into the electrical stimulation device category.

For basic unit characteristics, the subject device has some differences from predicate device #1; however, it is identical to predicate device #2 except for weight and dimensions which will not raise concern in safety or effectiveness.

For output specifications, the subject device is different from predicate devices in some items; however, those parameters are relatively similar and the subject device falls within the parameters of the two predicate devices. As the subject device complies with ANSI/AAMI ES60601-1 and IEC 60601-2-10, which means we have proved its safety as well as the effectiveness comparing with the predicate device. Therefore, the subject device and predicate devices are substantially equivalence on these parameters. The TENS output of the subject device is as safe and effective as the predicate devices.

14. Conclusion

After conducted 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, POCKET TENS (EP-300), is substantially equivalent to the predicate devices in safety and effectiveness.