April 2, 2025

Progenix LLC
Christian Hunt
President
Department 114
10304 Eaton Place, Suite 100
Fairfax, Virginia 22030

Re: K242460
Trade/Device Name: Progenix Select Stim
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: January 24, 2025
Received: January 24, 2025

Dear Mr. Hunt:

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
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)*

K242460

Device Name

Progenix Select Stim

Indications for Use *(Describe)*

TENS:
• 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.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Type of 510(k) submission: Traditional

Date of the summary prepared: Dec-30-2024

2. Submitter's Information

Submitter: Progenix LLC
Address: Department 114, 10304 Eaton Place, Suite 100, Fairfax VA 22030 United States
Contact Person: Christian Hunt
Email: progenixllc@gmail.com
Tel: (610) 800-11198

3. Subject Device Information

Trade Name: Progenix Select Stim (Model: PRO1205-OTC1)
Common Name: TENS, Stimulator for pain relief.
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Review Panel: Neurology
Product Code: NUH
Regulation Number: 21 CFR 882.5890
Device Classification: Class II
Use: Over-the-Counter Use (OTC)

4. The Predicate Device Information

Basic Information	**Predicate device**
Manufacturer	HIVOX BIOTEK INC.
Device Name	HIVOX OTC Electrical Stimulator
Model Number	EM49-1, EM49-2
510(k) Number	K190347, K171803
Product Code	NUH, NGX
Panel Code	Neurology
Regulation Number	21 CFR 882.5890
Regulation Class	Class II

5. Device Description / Design of the Device

The Progenix Select Stim (Model: PRO1205-OTC1) device is a portable, battery powered (9 V battery) two channel device designed to provide Transcutaneous Electrical Nerve Stimulation (TENS) for the purpose of the symptomatic relief of pain.

The device consists of the TENS stimulator, two lead wires and set of four Skin Electrodes. It provides 10 preset TENS treatment programmes. The programs include four modes of operation: Conventional TENS(Continuous), Burst Mode,

Modulation mode and HAN TENS. The device LCD screen shows the information of program, intensity level of each channel and operating time.

The electrode pads are cleared by FDA (510(k) number K160138). They are used as an accessory to the TENS device unit, to transmit electrical current to patient skin. The electrodes consist of biocompatible self-adhesive conductive application use. These electrodes are sized 50x50mm and are sold under the model number PRO5050.

6. Indication for Use

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.

7. **Technological characteristic and substantial equivalence**.

7.1. Basic Unit characteristic table

	Parameter description	New Device	Primary predicate device	SE
	Trade Name	Progenix Select Stim	HIVOX OTC Electrical Stimulator	N/A
	Device model	PRO1205-OTC1	EM49-1, EM49-2	
	510(k) Number	K242460	K190347, K171803	
1	Manufacturer	Progenix LLC	HIVOX BIOTEK INC.	N/A
2	Regulatory Information	882.5890	882.5890	SE
3	Classification	Class II	Class II	SE
4	Product Code	NUH	NUH NGX	SE
5	Review Panel	Neurology	Neurology	SE
6	General Classification	OTC	OTC	SE
7	Intended use	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.	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 stimulating healthy muscles in order to improve and facilitate muscle performance. .	SE
8	Apply parts of the body	Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom	Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom	SE
9	Power Source(s)	9V, 1xPP3 alkaline battery	4.5 V, 3 × AAA batteries	SE Note 1

	Parameter description	New Device	Primary predicate device	SE
	Trade Name	Progenix Select Stim	HIVOX OTC Electrical Stimulator	N/A
	Device model	PRO1205-OTC1	EM49-1, EM49-2	
	510(k) Number	K242460	K190347, K171803	
10	Method of Line Current Isolation	No line connection, Internal power source (BF type applied parts)	No line connection, Internal power source No line connection (BF type applied parts)	SE
11	Patient Leakage Current	/	/	/
11a	- Normal condition	3μA	6.0 μA	SE
11b	- Single fault condition	1μA	5.6 μA	SE
12	Number of Output Modes (version of a waveform produced by the the unit)	1 (Biphasic,rectangular)	1 (Biphasic,rectangular)	SE
13	Number of Output Channels	2	2	SE
14	Synchronous or alternating?	Synchronous	Synchronous	SE
15	Method of Channel Isolation	By electrical circuit and software	By electrical circuit and software	SE
16	Regulated Current or Regulated Voltage?	Regulated Current	Regulated Current	SE
17	Software / Firmware / Microprocessor Control?	Yes	Yes	SE
18	Automatic Overload Trip?	Yes	Yes	SE
19	Automatic No-Load Trip?	Yes	Yes	SE
20	Automatic Shut Off?	Yes	Yes	SE
21	Patient Override Control?	Yes	Yes	SE
22	Indicator Display:	/	/	/
22a	- On/Off Status?	Yes	Yes	SE
22b	- Low Battery?	Yes	Yes	SE
22c	- Voltage/Current Level?	Yes	Yes	SE
23	Timer Range (minutes)	30 or 60 minutes (program dependant)	5 to 100 minutes adjustable	SE
24	Compliance with Voluntary Standards?	YES • IEC 60601-1 • IEC60601-1-2 • IEC60601-1-6 • IEC60601-1-11 • IEC60601-2-10 • IEC62304	YES • ES60601-1 • IEC 60601-1-2 • IEC 60601-1-11 • IEC 60601-2-10	SE
25	Compliance with 21 CFR 898?	Yes	Yes	SE
26	Accessories	Self-adhesive electrodes, electrode wires,	Self-adhesive electrodes, electrode wires,	SE
27	Weight (g)	152g (including battery)	Approx. 117 (including belt clip and batteries)	SE Note 2
28	Dimensions (mm) [W x H x D]	119.2 mm x 69 mm x 28.7 mm	132 mm x 63 mm x 29.5 mm	
29	Housing Materials and Construction	Injection molding ABS plastic	Injection molding ABS plastic	SE

Comparison in details:

Note 1:
(Predicate device uses 4.5 V, 3 × AAA batteries as a power source.
This difference does not affect the safety and efficacy of the Progenix Select Stim which uses 9V battery)

Note 2:
The proposed device has passed the IEC 60601-1 test. The weight, dimensions, appearance of proposed device has is different from predicate devices, but these differences are insignificant and won't raise any new risk of safety and effectiveness.

7.2. Output Parameters Specification

No	Parameter description		Proposed device	Primary predicate device	SE
1	Trade Name		Progenix Select Stim	HIVOX OTC Electrical Stimulator	N/A
2	Device model		PRO1205-OTC1	EM49-1, EM49-2	
3	510(k) Number		K242460	K190347, K171803	
4	Waveform		Biphasic	Biphasic	SE
5	Shape		Rectangular	Rectangular	SE
6	Maximum Output Voltage (V)	@ 500Ω	40 V	100 V	SE Note 1
		@ 2 kΩ	100 V	180 V	
		@ 10 kΩ	145 V	250 V	
7	Maximum Output Current (mA)	@ 500Ω	80 mA	200 mA	SE Note 1
		@ 2 kΩ	50 mA	90 mA	
		@ 10 kΩ	19 mA	25 mA	
8	Pulse Width(μs)		50-200	50-450	SE Note 2
9	Frequency (hz)		2 – 100	1-150	SE Note 3
10	For interferential modes only: - Beat Frequency (Hz)		N/A	N/A	N/A
11	For multiphasic waveforms only: - Symmetrical phases?		Asymmetrical biphasic (DC zero)	*Not publicly available*	N/A
12	Net Charge (μC per pulse @ 500 Ω)		0	0	SE
13	Maximum Phase Charge (μC @ 500 Ω)		16 (This corresponds to the longest pulse (200μs) at the highest current (80mA))	45	SE Note 4
14	Maximum Current Density (mA/cm²@ 500Ω)		3.2 (Smallest conductive surface area=25 cm^2)	9.87* (conductive surface area=20.25cm^2)	SE Note 4 *Max current density was calculated by us using the max output current @ 500 ohms; (200 mA / 20.25 cm^2)
15	Maximum Power Density (W/cm²@ 500Ω)		0,0025 (At frequency of 100Hz, pulse width 200uS (P10) and current of 80mA)	0.0046	SE Note 4
16	Burst Mode		/	/	/
16a	- Pulses per burst		9	*Not publicly available*	SE
16b	- Bursts per second		2	*Not publicly available*	SE
16c	- Burst duration (seconds)		0.060(P07)	*Not publicly available*	SE
16d	- Duty Cycle [Line (b) x Line (c)]		0.12 (12% duty cycle)	*Not publicly available*	SE
17	ON Time (seconds)		N/A	*Not publicly available*	SE
18	OFF Time (seconds)		N/A	*Not publicly available*	SE

No	Parameter description	Proposed device	Primary predicate device	SE
1	Trade Name	Progenix Select Stim	HIVOX OTC Electrical Stimulator	N/A
2	Device model	PRO1205-OTC1	EM49-1, EM49-2	
3	510(k) Number	K242460	K190347, K171803	

Comparison:

Note 1:
There are some differences on the maximum output voltage and maximum Output current, between proposed device and predicate device K190347. The Progenix Select Stim features a lower maximum output voltage. This means that the device is safer and reduces risks associated with using the higher voltages while, nevertheless, remaining effective. The device has been tested to IEC60601-1 and IEC60601-2-10 standards and was found to comply with its requirements, demonstrating that the device is electrically safe for use by end users. Therefore, this difference does not affect the safety and efficacy of the device when used as labeled.

Note 2:
The pulse width range in proposed device is narrower but still within the lower end of the range used by the predicate device. Pulse widths within the 50 to 200 µs range are widely recognized as effective for stimulating sensory and motor nerves, which are the primary targets for therapeutic TENS device. Extended lower limit and reduced upper limit does not compromise the device's ability to deliver effective therapy, as studies have shown that pulse widths in this range are sufficient for pain relief. The narrower range may even help minimize the risk of discomfort associated with higher pulse widths, enhancing user safety.

Note 3:
The frequency range in proposed device is narrower, within the range of the predicate device and falls entirely within the range considered safe and effective for therapeutic electrical nerve stimulation. Frequencies from 2 to 100 Hz allow for stimulating with both low-frequency and medium-frequency applications. The exclusion of very high frequencies (>100 Hz) does not impact performance, as these frequencies are less commonly used for the intended therapeutic effects and may be less comfortable for users.

Note 4:

There are some differences on the maximum phase charge, maximum current density, maximum power density between the proposed device and the predicate device, K190347,but these parameters don't exceed the safety limit (<0.25Watts/cm²), Therefore, these differences won't raise any new safety and effectiveness risk. The differences are caused by fact that proposed device has lower max output and that bigger surface area of proposed smallest electrode. The electrodes are sized 50x50mm and are sold as model PRO5050.

The Progenix Select Stim model PRO1205-OTC1 demonstrates substantial equivalence to the predicate device, HIVOX OTC Electrical Stimulator (Models EM49-1 and EM49-2, K190347), based on a comparison of their technological characteristics. Both devices are handheld electrical stimulators designed for over-the-counter (OTC) use to provide electrical stimulation for temporary pain relief. The materials used in their construction, including biocompatible electrodes and housing components, are substantial equivalent, ensuring safety and compatibility with intended use. Neither device involves the use of chemicals or drugs.

In terms of energy source, the Progenix Select Stim, PRO1205 uses a single PP3 alkaline 9V battery, whereas the predicate device is powered by 3 x AAA batteries providing 4.5V. Despite this difference, both devices deliver low-voltage electrical impulses, and the change in energy source does not affect safety, performance, or compliance with applicable standards.

Regarding output specifications, the pulse width for the predicate device is 50 to 450 µs, and the frequency range is 1 to 150 Hz, while the Progenix Select Stim, PRO1205-OTC1 has a pulse width of 50 to 250 µs and a frequency range of 10 to 100 Hz. These differences result in slightly narrower ranges for the Progenix Select Stim, PRO1205-OTC1, but the specifications remain within the range of commonly accepted values for safe and effective electrical stimulation. The narrower pulse width and frequency ranges are aligned with the intended therapeutic effects of the Progenix Select Stim, PRO1205-OTC1 and do not introduce safety or performance concerns. Both devices comply with IEC 60601-1 (General Requirements for Basic Safety and Essential Performance) and IEC 60601-2-10 (Particular

Requirements for the Safety of Nerve and Muscle Stimulators), ensuring that the Progenix Select Stim, PRO1205-OTC1 operates safely within its intended parameters.

There are no differences in technological characteristics, including the revised output specifications, that raise new questions of safety or effectiveness. These comparisons confirm that the new device is substantially equivalent to the predicate device.

8. Non-clinical studies and tests performance.

Non-clinical tests have been conducted to verify that the transcutaneous electrical nerve stimulator meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the targeted device complies with the following standards:

- IEC60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-6: - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC60601-1-11, Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC60601-2-10, Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC62304 - Software life cycle processes
- Function test (Guidance Document for Powered Muscle Stimulator 510(K)s. Document issued on: June 9, 1999)

The body-contacting components of this device are electrode patches. We have directly purchased the electrode patches from qualified supplier which has obtained FDA clearance with a 510(k) number of K160138, so we have reason to believe that the electrode patches are safe for the users. The electrode patches comply to the following standards:

1) ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests for In Vitro Cytotoxicity.
2) ISO 10993-10,Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

9. Clinical Performance Data

Not applicable

10. Conclusion

After analysing non-clinical laboratory studies and safety testing data, it can be concluded that the Progenix Select Stim model PRO1205-OTC1 is substantially equivalent to the predicate device K190347.