April 20, 2026

Spinex, Inc.
Parag Gad, PhD
Chief Executive Officer
37917 Lavender Commons
Fremont, California 94536

Re: K253638
Trade/Device Name: xStep (xStep)
Regulation Number: 21 CFR 890.5851
Regulation Name: Transcutaneous Electrical Spine Stimulator To Improve Skeletal Muscle Strength And Sensation
Regulatory Class: Class II
Product Code: SDO
Dated: November 12, 2025
Received: November 19, 2025

Dear Parag Gad:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253638

Please provide the device trade name(s).

xStep (xStep)

Please provide your Indications for Use below.

The xStep™ is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive). The xStep™ device is for prescription use in patients ages 18-75 years old in a medical center.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K253638

(per 21 CFR §807.92)

1. Submitter Information

Submission type:	Traditional 510(k)
Company Name:	SpineX Inc.
Address	37917 Lavender Commons, Fremont, CA 94536, USA
Local Address	37917 Lavender Commons, Fremont, CA 94536, USA
Contact Person:	Parag Gad, PhD, CEO
Telephone:	+1 (408) 203-5061
Email:	parag@spinex.co
Date Prepared:	April 17, 2026

2. Device Identification

Trade Name:	xStep
Common Name:	Transcutaneous electrical spine stimulator
Product Code:	SDO
Regulatory Class:	Class II
Regulation Number	21 CFR 890.5851

3. Predicate Device

Predicate Manufacturer:	Onward
Medical Predicate Device:	ARC^{EX}
510(k) Number:	DEN240014

4. Device Description

The xStep™ is a medical device intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive). The xStep™ device is for prescription use in patients ages 18-75 years old in a medical center.

The xStep device consists of four components:

- xStep™ Stimulator (Part Number 030-0200)
- Charger (Part Number 030-0251)
- Electrode Cable Assembly (Part Number 030-0257)
- 1 Set Active electrodes (Axelgaard, Model Number CF3200, 1.25" Round)
- 1 Set Return electrodes (Axelgaard, Model Number UF2040, 2" x 4" Rectangle)

  Both electrodes are manufactured and have been previously cleared by FDA (K132422) for the same nature of body contact.
- 1 Storage Case (Part Number 030-0366)

Mechanism of Action:

Due to paralysis caused by an incomplete cervical spinal cord injury, the brain may either send abnormal motor signals to the spinal networks, or the signals from the brain may not reach the spinal networks; thus resulting in abnormal signals being projected to muscles. Motor dysfunction in individuals with incomplete spinal cord injury results in the inability to control hand muscles due to the aberrant neural connectivity between the brain and spinal cord. Thus, the descending commands from the brain generates abnormal signals among the spinal networks that increases the co-contraction of flexors and extensor muscles. In addition, abnormal proprioceptive signals ascend to activate multiple supraspinal nuclei, thus completing a continuous loop of maladaptive sensory-motor signals resulting in disordered networks that reflect the initial supraspinal pathology.

The electrical stimulation delivered by the xStep device is intended to be delivered transcutaneously, and the active electrodes (K132422) are designed to be placed in direct contact with intact skin, in appropriate locations along or near the spine that activate the nerves in the spinal cord responsible for controlling motor and sensory function of that hand that is impaired from incomplete paralysis due to spinal cord injury.

xStep is built around a custom waveform that consists of 2 unique frequencies, **the burst frequency** and **the carrier frequency**.

- The *burst* or *therapeutic* frequency activates the neurons in the spinal cord and in turn the targeted muscles.
- The high-frequency *carrier* wave that creates an analgesic effect on the superficial skin layers allowing the burst frequency to penetrate and reach the deeper neurons in the spinal cord.

The degree of penetration into the spinal cord and the number of neurons activated is based on the intensity of stimulation. However, despite the higher currents needed to activate nerves present at deeper locations, no superficial pain or discomfort is experienced because of the coordinated function of the burst and carrier waves. xStep therapy activates the nerves in the spinal cord resulting in improved coordination of muscle activity and neuroplasticity being induced in the brain and spinal cord leading to improved hand sensation and strength in individuals with incomplete spinal cord injury. It is intended to be used in conjunction with functional task practice in the clinic to improve hand sensation and strength by inducing neuroplasticity in the nervous system in individuals with chronic, non-progressive neurological deficits resulting from incomplete paralysis due to SCI

Description of how the device functions

xStep is built around a custom waveform that consists of 2 unique frequencies, the burst frequency and the carrier frequency. The burst or therapeutic frequency 'tunes' the spinal neurons and in turn the targeted muscles towards an activation or inhibition pattern based on the proprioceptive (sensory) information received during the functional task being performed and/or the descending brain signals (voluntary commands). In the case of a patient with incomplete cervical spinal cord injury, the tuning of the spinal cord could result in assisting the patient to increase strength in their hands, while the sensory information from the hand informs the spinal cord and brain that the hands are performing the task. This results in the spinal cord (which is now excited due to xStep therapy) triggering activation of the hands muscles allowing the patient to complete the task.

The second component is a high-frequency carrier wave that creates an analgesic effect on the superficial skin layers allowing the burst frequency to penetrate and reach the deeper neurons in the spinal cord. The degree of penetration into the spinal cord and the number of neurons activated is based on the intensity of stimulation. However, despite the higher currents needed to activate nerves present at deeper locations, no superficial pain or discomfort is experienced because of the coordinated function of the burst and carrier waves. In comparison, off-the-shelf stimulators (TENS, muscle stimulators, etc.) use only a single burst frequency and are unable to activate deeper nerve structures, stimulating only superficial muscles and nerves and NOT the targeted spinal neurons.

Any novel technology or features

The xStep device does not introduce any new or novel technologies, features, or mechanisms of action when compared to the predicate device, ARC-EX by ONWARD. Both devices utilize non-invasive, targeted transcutaneous electrical stimulation delivered through external hydrogel electrodes to activate spinal neural circuits below the level of injury. The core technological characteristics—such as stimulation waveform, delivery method, electrode configuration, and intended use—are functionally equivalent. The xStep device operates using the same fundamental principles of spinal cord stimulation and shares the same therapeutic objective: to improve hand muscle strength and sensation by inducing neuroplasticity in the nervous system in individuals with chronic, non-progressive neurological deficits resulting from incomplete paralysis due to SCI. As such, the xStep device does not raise new questions of safety or effectiveness relative to the predicate device.

5. Intended Use / Indications for Use

Indications for Use

The xStep™ is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive). The xStep™ device is for prescription use in patients ages 18-75 years old in a medical center.

Intended Use

The xStep™ is intended for individuals aged 18-75 old with chronic, non-progressive, incomplete (Grade B, C or D on the American Spinal Injury Association (ASIA) Impairment Scale (AIS)) cervical spinal cord injury (C2-C8 inclusive).

Patient Population

The xStep™ device is a medical device and is intended to treat patients with chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive). The xStep™ device is for prescription use in patients ages 18-75 years old in a medical center.

6. Substantial Equivalence Discussion

The following comparison demonstrates that the xStep device is substantially equivalent to the predicate device in terms of intended use, indications for use, and technological characteristics. Where technological differences exist, the differences represent parameter values within clinically used ranges and within the range of the predicate. Non-clinical performance testing confirms that these differences do not raise new questions of safety or effectiveness

Parameter	**ARCex**	**xStep**	**Comparison**
Waveform	Monophasic or Biphasic	Monophasic and Delayed Biphasic	Identical
Biphasic amplitude	0-250 mA	0-200 mA	Substantially Equivalent
Intra-burst pulse repetition frequency	10000-20000 Hz	10000 Hz	Substantially Equivalent
Intra-burst pulse width	50 or 100 µs	100 µs	Substantially Equivalent
Carrier frequency	5000 or 10000 Hz	10000 Hz	Substantially Equivalent
Frequency	0.2-100 Hz	30 Hz	Substantially Equivalent
Pulse (burst) width	0.1-5 ms	1 ms	Substantially Equivalent
Ramp-up duration	2-60 s	Manual	Substantially Equivalent
Program duration	1-180 min	60 min	Substantially Equivalent
Channels	4	2	Substantially Equivalent
Output current	Rectangular pulses with carrier frequency	Rectangular pulses with carrier frequency	Identical
Display	Digital	Digital	Identical
Enclosure	ABS plastic	ABS plastic	Identical
Control interface	Manual button	Manual button	Identical
Electrodes	Axelgaard PALS (K132422)	Axelgaard PALS (K132422)	Identical
Power source	Rechargeable battery	Rechargeable battery	Identical
EMC standards	IEC 60601-1-2, IEC 60601-4-2	IEC 60601-1-2, IEC 60601-4-2	Identical
Electrical/mechanical safety	IEC 60601-1, IEC 60601-2-10	IEC 60601-1, IEC 60601-2-10	Identical
Battery safety	IEC 62133-2:2017, UN38.3, EN IEC 55035	IEC 62133-2:2017, UN38.3, EN IEC 55035	Identical
Software documentation level	Enhanced	Enhanced	Identical

The minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the xStep System relative to the predicate, and the non-clinical performance testing (Section 7) demonstrates acceptable safety and performance to support substantial equivalence

7. Performance Data

Non-clinical testing was conducted to support substantial equivalence:

- Electrical Safety and EMC: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ANSI C63.4
- Electrical Stimulation Parameter Characterization: Verification of waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse; maximum phase charge, maximum current density, maximum average current, and maximum average power density, polarity, and rise/fall time
- Software Verification and Validation: IEC 62304, per FDA guidance
- Battery Safety: IEC 62133-2
- Mechanical/Packaging Testing (per IEC 60601-1): Push, impact, and drop testing
- Cybersecurity: Not applicable; the xStep device has no communication capabilities, no remote access, and stores no sensitive health information, per FDA guidance (October 2023)

The xStep device is provided non-sterile with an expected lifetime of 3 years.

Electrodes (K132422) are provided sterile by the manufacturer with a labeled shelf life of 2 years.

8. Conclusion

The xStep™ device has: - The same intended use, - Similar technological characteristics, and - No new questions of safety or effectiveness.

Therefore, xStep is substantially equivalent to the predicate device ARC ex™ (DEN240014).