March 27, 2026

ANEUVO
Amelia Striegel
Regulatory Affairs Manager
10940 Wilshire Blvd.
Suite 2030
Los Angeles, California 90024

Re: K252893
Trade/Device Name: ExaStim® Stimulation System (EXA-001); ExaStim® Stimulation System (EXA-011); ReCure® Electrode Pad (PAD-003); ReCure® Electrode Pad (PAD-013)
Regulation Number: 21 CFR 890.5851
Regulation Name: Transcutaneous Electrical Spine Stimulator To Improve Skeletal Muscle Strength And Sensation
Regulatory Class: Class II
Product Codes: SDO, GXY
Dated: February 23, 2026
Received: February 23, 2026

Dear Amelia Striegel:

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,

Digitally signed by
ZACHARY MCKINNEY -S
Date: 2026.03.27
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for 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

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.

510(k) Number *(if known)*
K252893

Device Name
ExaStim® Stimulation System (EXA-001); ExaStim® Stimulation System (EXA-011);
ReCure® Electrode Pad (PAD-003); ReCure® Electrode Pad (PAD-013)

Indications for Use *(Describe)*
The ExaStim Stimulation System is indicated for the improvement of hand sensation and strength in individuals between 18 and 75 years old who present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury, when used in conjunction with functional task practice.

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
K252893
March 27, 2026

I. **Company:**

ANEUVO
10940 Wilshire Blvd.
Suite 2030
Los Angeles, CA 90024
Telephone: (424) 256-2194

Contact: Amelia Striegel (Primary)
Regulatory Affairs Manager
Telephone: (424) 256-2194

II. **Proprietary Trade Name:** ExaStim Stimulation System

III. Classification Name: Transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation (21 CFR 890.5851)

IV. Classification: Class II

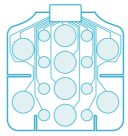
V. Product Codes: SDO (21 CFR 890.5851), GXY (21 CFR 882.1320)

VI. Product Description

The ExaStim® Stimulation System is designed to deliver transcutaneous electrical spinal stimulation for therapeutic use in individuals with incomplete spinal cord injury (SCI). The ExaStim Portable Stimulator is a battery-operated medical device composed of specialized electronics and embedded firmware. It emits stimulation according to parameters configured by the ExaStim Programmer by a clinician.

The ExaStim Stimulation System consists of the components described in Table 1.

Table 1: ExaStim Stimulation System Components Summary

	Part Name	Description
	ReCure® Electrode Pad	Non-invasive 16-channel multi-electrode array
	ExaStim® Portable Stimulator	Generates and delivers controlled electrical stimulation to the spinal cord and dorsal roots via the ReCure® Electrode Pad based on commands from the ExaStim® Programmer
	ReCure® Stimulation Cable	Connects the ExaStim® Portable Stimulator to the ReCure Electrode Pad
	ExaStim® Return Electrode Cable	Connects the return electrodes (i.e., PALS Neurostimulation Electrode) to the ExaStim® Portable Stimulator
	ExaStim® Programmer	Bluetooth‡-enabled mobile digital device preloaded with proprietary ExaStim® Programming Software; includes a charging cable.
	ExaStim® Charging Cable	Charger used to recharge the battery of the ExaStim Portable Stimulator

In addition to the components listed above, the system requires two PALS‡ Neurostimulation Electrodes manufactured by Axelgaard, as shown in Table 2 which are not included with the system.

Table 2: Additional required components

	Part Name	Catalog Number	Description
	PALS‡ Neurostimulation Electrode	895240	Return electrodes

VII. Indications for Use:

The ExaStim Stimulation System is indicated for the improvement of hand sensation and strength in individuals between 18 and 75 years old who present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury, when used in conjunction with functional task practice.

VIII. Comparison of Technological Characteristics

Table 3: Summary Comparison of ExaStim Stimulation System to Predicate Device

Item	**ExaStim® Stimulation System (Subject)**	**ARC^{EX} System (Predicate) (DEN240014)**	**Comparison**
Intended Use	The ExaStim Stimulation System is a portable, non-invasive, medical device system that delivers multi-channel transcutaneous electrical spinal stimulation. ExaStim is intended to be used in conjunction with functional task practice.	The ARC^{EX} System 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).	Similar
Indications for Use	The ExaStim Stimulation System is indicated for the improvement of hand sensation and strength in individuals between 18 and 75 years old who present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury, when used in conjunction with functional task practice.		
Mode of Action	Electrical stimulation via surface electrodes.	Electrical stimulation via surface electrodes.	Same

Item	ExaStim® Stimulation System (Subject)	ARC^{EX} System (Predicate) (DEN240014)	Comparison
IP Class	IP22	IP22	Same
Applied part	Type BF	Type BF	Same
Regulated Current/Voltage	Current	Current	Same
Waveform	Biphasic	Monophasic or Biphasic	Similar
Waveshape	Rectangular	Rectangular	Same
Biphasic Stimulation Maximum Current	150 mA	250 mA	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.
Biphasic Stimulation Maximum Voltage	75 V @ 500 Ω 75 V @ 1 kΩ	125 V @ 500 Ω	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance

Item	ExaStim® Stimulation System (Subject)	ARC^{EX} System (Predicate) (DEN240014)	Comparison
			testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.
Pulse Frequency	1 Hz – 100 Hz	0.2 Hz – 100 Hz	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.
Pulse Width	0.3 ms – 1 ms	0.1 ms – 5 ms	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and

Item	ExaStim® Stimulation System (Subject)	ARC^{EX} System (Predicate) (DEN240014)	Comparison
			performance to support substantial equivalence.
Ramp-up Duration	2 s – 1 hr	2 s – 60 s. For specific stimulation settings, the ramp-up duration can be lengthened up to 125 s.	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.
Program Duration	1 s – 180 min	1 min – 180 min	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.

Item	ExaStim® Stimulation System (Subject)	ARC^{EX} System (Predicate) (DEN240014)	Comparison
Output channels	Up to 16	Up to 4	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.
Active electrode	ReCure Electrode Pad	Axelgaard PALS electrode 879100 (K132422)	Different. Minor differences in design specifications and stimulation parameters do not significantly affect the safety and effectiveness of the ExaStim System relative to the predicate, and the non-clinical performance testing (Section X) demonstrates acceptable safety and performance to support substantial equivalence.
Compatible return electrode	Axelgaard PALS electrode 895240 (K132422)	Axelgaard PALS electrode 895240 (K132422)	Same

Although the subject device separates the Intended Use and the Indications for Use for clarity, the overall indications for use are equivalent. Both devices are indicated for the improvement of hand sensation and strength in individuals with chronic, non-progressive neurological deficits resulting from an incomplete spinal cord injury and are to be used in conjunction with functional task practice.

Table 4: Summary Comparison of ReCure Electrode Pad to Reference Device

Item	**ReCure® Electrode Pad (Subject)**	**Axelgaard Electrode 879100 (Reference Device) (K132422)**	**Comparison**
Technology	Cutaneous multielectrode pad that conducts an electrical signal from a neurostimulation device through a cable, which is dispersed across a stretchable conductive silver ink printed on a TPU substrate, then transmitted through the conductive adhesive gel to the surface of the user's skin.	Cutaneous electrode that conducts an electrical signal from a neurostimulation device through a lead wire, which is dispersed from the lead wire across a stretchable conductive fabric, then transmitted through the conductive adhesive gel to the surface of the user's skin.	Similar
Principles of Operation	Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.	Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.	Same

Item	ReCure® Electrode Pad (Subject)	Axelgaard Electrode 879100 (Reference Device) (K132422)	Comparison
Maximum Allowable Power Density	0.245 W/cm^2	0.1 W/cm^2	Different. Neither the subject nor the reference device exceeds the maximum power density <0.25 W/cm^2 noted in the Guidance Document for Powered Muscle Stimulator 510(k)s.

Features/ Materials	Four basic components:
	• Top cover material
	• Cable connection
	  ○ Cable has insulation on female connector
	• Stretchable conductive ink
	• Conductive hydrogel
		Four basic components:
		• Top cover material
		• Lead wire connection
		  ○ Lead wire has insulation on female connector
		• Stretchable conductive fabric
		• Conductive hydrogel
			Similar

IX. Identification of Legally Marketed Device

Predicate: ARC^{EX} System (DEN240014)
Reference: PALS Neurostimulation Electrodes (K132422)

X. Discussion of the Performance Testing

Testing conducted to demonstrate equivalency of the subject device to the predicate is summarized as follows:

- Characterization of Electrical Stimulation Parameters including the following: waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, maximum phase charge, maximum current density, maximum average current, maximum average power density
- Characterization of the Impedance Monitoring System including impedance measurement and stimulation control

- Characterization of Electrode Performance including electrical performance, adhesive integrity, shelf life, reusability, and current distribution of electrode surface area
- Electromagnetic Compatibility (EMC), Electrical Safety, and Performance Testing (IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-10)
- Wireless Coexistence Testing (ANSI C63.27)
- Human Factors Validation (IEC 62366-1, IEC 60601-1-6)
- Packaging Verification (ASTM D4332, ASTM D4169-22)
- Biocompatibility (ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23)

XI. Conclusions

Non-clinical testing and technological comparison support the substantial equivalence of the subject device, the ExaStim Stimulation System, to the identified predicate device.