November 14, 2025

Onward Medical Inc.
Nathalie Gilat
Senior Director, Clinical and Regulatory Affairs
50 Milk Street
Boston, Massachusetts 02109

Re: K251821
Trade/Device Name: ARC-EX System
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: October 14, 2025
Received: October 14, 2025

Dear Nathalie Gilat:

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,

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.	K251821

Please provide the device trade name(s).

ARC-EX System

Please provide your Indications for Use below.

The ARC-EX System is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home 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 ARC-EX System is intended to be operated in medical centers by Rehabilitation Professionals and at home by Patients and Persons Providing Assistance to the Patient as needed.

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) #: K251821

510(k) Summary

Prepared on: 2025-10-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Onward Medical Inc.
Applicant Address	50 Milk Street, Boston MA 02109 United States
Applicant Contact Telephone	5853639124
Applicant Contact	Mrs. Nathalie Gilat
Applicant Contact Email	nathalie.gilat@onwd.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ARC-EX System
Common Name	ARC-EX System
Classification Name	Transcutaneous Electrical Spine Stimulator To Improve Skeletal Muscle Strength And Sensation
Regulation Number	21 CFR 890.5851
Product Code(s)	SDO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
DEN240014	ARC-EX System	SDO

Device Description Summary

21 CFR 807.92(a)(4)

The ARC-EX System is a medical device that delivers transcutaneous programmed, Carrier Frequency-enabled electrical spinal cord stimulation (ARC-EX Therapy). The System is intended to be used in conjunction with functional task practice in the clinic and with take-home exercises in the home to improve hand sensation and strength in individuals with cervical spinal cord injury (SCI).

The stimulation is intended to be delivered transcutaneously and the active electrodes are intended to be placed in direct contact with intact skin, in appropriate locations along or near the spine to elicit desired outcomes. The ARC-EX System is intended to be used in a medical center setting by patients and their rehabilitation professionals, and at home by Patients and Persons providing assistance to the patient as needed.

The primary components of the ARC-EX System are:

• ARC-EX Stimulator is an internally powered device equipped with a rechargeable battery. It generates and delivers electrical stimulation to the Electrodes based on commands received from the ARC-EX Programmer.

• ARC-EX Stimulator Charger is a wired charger used to recharge the Stimulator battery.

• ARC-EX Splitter Box is used to connect and transmit current from the Stimulator to the Electrodes (via the Extension Cables).

• ARC-EX Extension Cables are used to connect the Splitter Box to the Electrodes. Two different Extension cable lengths are provided: short Extension Cables (50 cm/19.7 inches long) long Extension Cables (100 cm/39.4 inches long)

• ARC-EX Programmer is an off-the-shelf tablet with the ARC-EX PRO app or the myARC-EX app pre-installed and can be used by the

Rehabilitation Professional and the Patient exchange data with the Stimulator.

• Programmer Charger (Tablet Charger) is used to recharge the Tablet battery.

• ARC-EX Case is intended for transportation and storage, in between use, of the ARC-EX System.

The ARC-EX System is intended to be used with the FDA-cleared Axelgaard PALS electrodes (KI 32422).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ARC-EX System is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home 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 ARC-EX System is intended to be operated in medical centers by Rehabilitation Professionals and at home by Patients and Persons Providing Assistance to the Patient as needed.

Indications for Use Comparison

21 CFR 807.92(a)(5)

510(k) Substantial Equivalence Comparison

Intended Use:
The intended use of the subject device is as a transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation. The device applies electrical current via electrodes over the spine to improve muscle strength and sensation after neurological deficit. This intended use is the same as that of the predicate device, and therefore is considered identical.

Indications for Use:
The ARC-EX System is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home 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 ARC-EX System is intended to be operated in medical centers by Rehabilitation Professionals and at home by Patients and Persons Providing Assistance to the Patient as needed.

The predicate device is indicated for the same population and purpose, but excludes home use.
The addition of home use with take-home exercises is a natural extension of functional task practice in the clinic and does not alter the intended use or raise new questions of safety or effectiveness. This difference is not considered significant.

Technological Comparison

21 CFR 807.92(a)(6)

510(k) Substantial Equivalence Comparison

Manufacturer:
Both the subject and predicate devices are manufactured by ONWARD Medical. Therefore, the manufacturer is identical.

Regulation Number:
Both devices are classified under 21 CFR 890.5851. This classification is identical.

Regulation Name:
The regulation name for both devices is "Transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation." This designation is the same for both, and therefore identical.

Product Code:
Both devices share the product code SDO.

Device Classification:
The subject and predicate devices are both Class II medical devices.

Intended Use:
The intended use of the subject device is as a transcutaneous electrical spine stimulator to improve skeletal muscle strength and sensation. The device applies electrical current via electrodes over the spine to improve muscle strength and sensation after neurological deficit.

This intended use is the same as that of the predicate device, and therefore is considered identical.

Indications for Use:
he ARC-EX System is intended to deliver programmed transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home 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 ARC-EX System is intended to be operated in medical centers by Rehabilitation Professionals and at home by Patients and Persons Providing Assistance to the Patient as needed.
The predicate device is indicated for the same population and purpose, but excludes home use.
The addition of home use with take-home exercises is a natural extension of functional task practice in the clinic and does not alter the intended use or raise new questions of safety or effectiveness. This difference is not considered significant.

Principle of Operation:
Both devices use transcutaneous electrical stimulation to activate viable but dormant neurons, strengthening motor and sensory pathways with training. The principle of operation is identical.

Components:
The subject device includes the following components: Stimulator, Charger & Adapter, Splitter Box, Extension Cables, Programmer, Programmer Charger, and Case. These components are the same as those in the predicate device and are therefore identical.

Stimulation Parameters:
Both devices support monophasic and biphasic stimulation. Amplitude ranges from 0-250 mA; pulse width ranges from 0.1-5 ms; frequency ranges from 0.2-100 Hz. Various burst and carrier settings are available.
The only difference is in programming access control, which limits patient access in the subject device for safety. Therefore, the devices are considered identical in stimulation performance.

Energy Source:
Both devices are powered by a rechargeable lithium-ion battery (10.8V, 3.2Ah, 37W) and include an AC/DC adapter (15VDC, 4A). This is identical.

Output Specifications:
Maximum output for both devices includes 250 VDC and 250 mA (biphasic), 100 mA (monophasic), with a net charge of 0 µC. These specifications are identical.

Current Density / Power Density:
For biphasic stimulation: 10.75 mA/cm^2 and 0.1 W/cm^2•
For monophasic stimulation: 8.4 mA/cm^2 and 0.06 W/cm^2•
These values are the same between devices and are thus considered identical.

Performance Standards:
The subject and predicate devices conform to the following standards: ANSI/AAMI ES60601-1, HA60601-1-11, IEC 60601-1-6, IEC 60601-2-10, and IEC 62304. This conformity is identical.

Biocompatibility:
Both devices are used externally with intact skin and are constructed using the same materials: silicone, polyamide, and polyurethane. This is identical.

Software Subcomponents:
The subject device includes the ARC-EX PRO app for professional use, the MyARCEX app for home use, and stimulator firmware.
The predicate device includes only the ARC-EX PRO app and stimulator firmware.
The addition of the MyARCEX app in the subject device is considered equivalent. Programming access in the home-use app is restricted to settings predefined by healthcare professionals. No new risks are introduced, and the change does not affect safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The changes being submitted in this 510(k) notification do not impact any non clinical like 60601 testing These aspects of the device remain consistent with the version that was previously reviewed and granted market authorization under De Novo DEN240014.

The modifications outlined in this 510(k) are limited to extension of the intended use to include use of the device at home and the Software and labelling being updated to reflect this. These changes do not affect the device's, fundamental scientific technology, or safety and effectiveness profile. Accordingly, the information provided in the previously cleared De Novo submission remains valid and applicable, and no new data or assessments are necessary for the referenced sections. Therefore, the subject device is substantially equivalent to the predicate.