

**K251821 ARC-EX System**Nov 14, 2025  
154 days to decisionK251821 · Product code: **SDO** · Neurology  
Source: <https://www.510kdatabase.net/k251821/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcutaneous Electrical Spine Stimulator To Improve Skeletal Muscle Strength And Sensation (SDO)
Date received	Jun 13, 2025
Decision date	Nov 14, 2025
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Onward Medical, Inc.</b>
Location	Boston, MA, US
Contact	Nathalie Gilat
510(k) history	2 submissions · 1 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251821/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026