

K253638 xStep (xStep)Apr 20, 2026
152 days to decisionK253638 · Product code: **SDO** · Physical MedicineSource: <https://www.510kdatabase.net/k253638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcutaneous Electrical Spine Stimulator To Improve Skeletal Muscle Strength And Sensation (SDO)
Date received	Nov 19, 2025
Decision date	Apr 20, 2026
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spinex, Inc.
Location	Fremont, CA, US
Contact	Parag Gad
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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