

K253926 DiacoreApr 10, 2026
123 days to decisionK253926 · Product code: **NGX** · Physical Medicine
Source: <https://www.510kdatabase.net/k253926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Dec 8, 2025
Decision date	Apr 10, 2026
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ShenB Co., Ltd.
Location	Seongdong-Gu, KR
Contact	Sun Young Kang
510(k) history	11 submissions · 11 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	Hoy & Associates Regulatory Consulting, LLC
Contact	Connie Hoy

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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