

K251746 Pure ImpactJul 2, 2025
26 days to decisionK251746 · Product code: **NGX** · Neurology
Source: <https://www.510kdatabase.net/k251746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jun 6, 2025
Decision date	Jul 2, 2025
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sofwave Medical, Ltd.
Location	Yokneam, IL
Contact	Ruthie Amir
510(k) history	12 submissions · 12 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

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

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