

**K241685 SofWave System**Aug 7, 2024  
57 days to decisionK241685 · Product code: **NGX** · Neurology  
Source: <https://www.510kdatabase.net/k241685/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jun 11, 2024
Decision date	Aug 7, 2024
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241685/> 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 14, 2026