

**K243165 Limfa Therapy System (Limfa Therapy)**May 15, 2025  
227 days to decisionK243165 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k243165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 30, 2024
Decision date	May 15, 2025
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Eywa Srl</b>
Location	Rimini, IT
Contact	Tommaso Faiella
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Eywa Srl America</b>
Contact	Thomas Lawson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243165/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026