

**K253636 Zionic Pro Max (EMS)**Mar 12, 2026  
113 days to decisionK253636 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k253636/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Nov 19, 2025
Decision date	Mar 12, 2026
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Termosalud S.L.</b>
Location	Gijon, ES
Contact	Cristina Cifuentes
510(k) history	2 submissions · 2 cleared · 2025-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hoy &amp; Associates Regulatory Consulting, LLC</b>
Contact	Connie Hoy

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/k253636/> 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 14, 2026