

K243488 VMAT PROFeb 6, 2025
86 days to decisionK243488 · Product code: **ISA** · Physical Medicine
Source: <https://www.510kdatabase.net/k243488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Therapeutic, Electric (ISA)
Date received	Nov 12, 2024
Decision date	Feb 6, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Termosalud
Location	Gijon, ES
Contact	Christina Cifuentes Pantoja
510(k) history	5 submissions · 5 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Hoy and Associates Regulatory Consultants
Contact	Aubrey Thompson

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.netDevice record: <https://www.510kdatabase.net/k243488/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026