FDA 510(k) Premarket Notification

K243716 Zionic Pro Max (Radiofrequency)

CLEARED

May 28, 2025
177 days to decision

K243716 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243716/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Dec 2, 2024
Decision date	May 28, 2025
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hoy and Associates Regulatory Consulting**
Contact	Aubrey Thompson

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