

K241733 HEBE (NP0000763)Apr 16, 2025
303 days to decisionK241733 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Jun 17, 2024
Decision date	Apr 16, 2025
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Novasonix Technology S.L.
Location	Granollers, ES
Contact	Carlos Navarro
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Freyr, Inc.
Contact	Shilpa Gampa

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

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