

K260647 SPECCHIOApr 2, 2026
34 days to decisionK260647 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Feb 27, 2026
Decision date	Apr 2, 2026
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	El.En S.P.A.
Location	Hopkinton, MA, US
Contact	Peruzzi Paolo
510(k) history	15 submissions · 15 cleared · 2014-2026

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