

K250734 OptiLUV DeviceSep 10, 2025
183 days to decisionK250734 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250734/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Mar 11, 2025
Decision date	Sep 10, 2025
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pollogen, Ltd.
Location	Binyamina, IL
Contact	Smith Karen
510(k) history	18 submissions · 18 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	BioVision , Ltd.
Contact	Elissa Burg

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250734/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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