

**K243055 Préime DermaFacial Collagen+**Apr 15, 2025  
200 days to decisionK243055 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243055/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Sep 27, 2024
Decision date	Apr 15, 2025
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>EMA Aesthetics , Ltd.</b>
Location	Dublin 2, IE
Contact	Alice Daniels
510(k) history	2 submissions · 2 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243055/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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