

K243072 Préime DermaFacial (MicroT)Apr 1, 2025
186 days to decisionK243072 · Product code: **NFO** · Neurology
Source: <https://www.510kdatabase.net/k243072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Sep 27, 2024
Decision date	Apr 1, 2025
Days to decision	186 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243072/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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