

K243472 1NEED ProMar 19, 2025
131 days to decisionK243472 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Nov 8, 2024
Decision date	Mar 19, 2025
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Campomats S.R.L.
Location	Riccione, IT
Contact	Mats Erik Andreasson
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Whitelab S.R.L.
Contact	Chiara Violini

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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