FDA 510(k) Premarket Notification

CLEARED

K243800 PRO Pen Microneedling System (6883)

Aug 25, 2025
257 days to decision

K243800 · Product code: **QAI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Microneedle Device (QAI)
Date received	Dec 11, 2024
Decision date	Aug 25, 2025
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dermalogica, LLC**
Location	Carson, CA, US
Contact	Nelson Torres
Website	http://www.dermalogica.com
510(k) history	1 submissions · 1 cleared · 2025-2025

Dermalogica, LLC is a professional-grade skin care company with a manufacturing facility in Carson, US. The brand specializes in dermatological skin care products and has expanded into medical device innovation. The company has received FDA 510(k) clearance from total submission. Dermalogica's cleared device falls within the General & Plastic Surgery category. The company achieved its first FDA 510(k) clearance in 2025 and remains active in the medical device space. Dermalogica's FDA-cleared device portfolio includes advanced treatment systems designed for professional ae...