

K252568 New Day Skin SprayJan 23, 2026
162 days to decisionK252568 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Aug 14, 2025
Decision date	Jan 23, 2026
Days to decision	162 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Silk Holdings, Inc.
Location	Needham, MA, US
Contact	Suzanne Cheang
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252568/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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