

K250115 Hemastyl(™) Wound DressingOct 14, 2025
271 days to decisionK250115 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jan 16, 2025
Decision date	Oct 14, 2025
Days to decision	271 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rapid Nexus Nanotech Wound Solutions, Inc.
Location	Brea, CA, US
Contact	Margaret Kalmeta
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Schuler Medical Device
Contact	Denise Holliday

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026