

**K243457 Nixall Antimicrobial Solutions™ Skin & Wound Hydrogel**May 2, 2025  
176 days to decisionK243457 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243457/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 7, 2024
Decision date	May 2, 2025
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Seriously Clean, Ltd.</b>
Location	Nixa, MO, US
Contact	Kip Glass
510(k) history	2 submissions · 2 cleared · 2012-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Compliance Associates</b>
Contact	Jordan Elder

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243457/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026