

**K250890 SBC1 Cream**Jan 12, 2026  
293 days to decisionK250890 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k250890/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Mar 25, 2025
Decision date	Jan 12, 2026
Days to decision	293 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sioxmed, LLC</b>
Location	Clemmons, NC, US
Contact	Mitchell Dellinger
Website	<a href="https://sioxmed.com">https://sioxmed.com</a>
510(k) history	5 submissions · 5 cleared · 2022-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Propharma</b>
Contact	Jennifer Daudelin

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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250890/> 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 14, 2026