

**K243001 Sterile Water USP and Sterile 0.9% Normal Saline USP**Mar 6, 2025  
161 days to decisionK243001 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 26, 2024
Decision date	Mar 6, 2025
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Laboratorios Biogalenic S.A. DE C.V.</b>
Location	San Salvador, SV
Contact	Roberto Quiñonez
510(k) history	3 submissions · 3 cleared · 2025-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Liberty Management Group , Ltd.</b>
Contact	Manoj Zacharias

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/k243001/> 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