

**K161311 USP Sterile Water, 120 mL cup, USP Sterile Normal Saline (0.9% sodium chloride), 120 mL cup, USP Sterile Water, 100 mL, 250 mL and 500 mL bottles, USP Sterile Normal Saline (0.9% sodium chloride), 100 mL, 250 mL and 500 mL bottles**Aug 29, 2016  
111 days to decisionK161311 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161311/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 10, 2016
Decision date	Aug 29, 2016
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Strukmyer Medical, LLC</b>
Location	Mesquite, TX, US
Contact	ROBERT DELK
510(k) history	2 submissions · 2 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161311/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026