

**K230190 Polyver Silver Alginate Dressing (Prescription and OTC)**Nov 17, 2023  
297 days to decisionK230190 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230190/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jan 24, 2023
Decision date	Nov 17, 2023
Days to decision	297 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roosin Medical Co., Ltd.</b>
Location	Taizhou, CN
Contact	Dayong Chen
510(k) history	3 submissions · 3 cleared · 2019-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manton Business and Technology Services</b>
Contact	Charles Shen

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/k230190/>. 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 25, 2026