

**K231564 Skin and Wound Cleanser**Nov 10, 2023  
163 days to decisionK231564 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231564/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 31, 2023
Decision date	Nov 10, 2023
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Winner Medical Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Mingni Liu
510(k) history	18 submissions · 18 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231564/> 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 14, 2026