

**K243415 Granudacyn® Wound Irrigation Solution**Jul 22, 2025  
263 days to decisionK243415 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243415/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 1, 2024
Decision date	Jul 22, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>P.G.F. Industry Solutions GmbH</b>
Location	Elixhausen, AT
Contact	Peter Fritz
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Molnycke Health Care Us, LLC</b>
Contact	Leonard Stewart

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/k243415/> 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