

**K254191 IWD-GeI™**Apr 7, 2026  
105 days to decisionK254191 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k254191/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Dec 23, 2025
Decision date	Apr 7, 2026
Days to decision	105 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>InnovaCorium, Inc.</b>
Location	Gainesville, FL, US
Contact	Marcelo Buzzi
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254191/> 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 13, 2026