

**K260551 HemosIL Factor V Leiden (APC Resistance V)**Mar 20, 2026  
30 days to decisionK260551 · Product code: **GGW** · Hematology  
Source: <https://www.510kdatabase.net/k260551/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Feb 18, 2026
Decision date	Mar 20, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentation Laboratory (IL) Co.</b>
Location	Bedford, MA, US
Contact	Kirivann Chhoeun
510(k) history	5 submissions · 5 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260551/> 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