

**K243374 HemosIL CL HIT-IgG(PF4-H)**Jan 28, 2025  
90 days to decisionK243374 · Product code: **LCO** · Hematology  
Source: <https://www.510kdatabase.net/k243374/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Platelet Factor 4 Radioimmunoassay (LCO)
Date received	Oct 30, 2024
Decision date	Jan 28, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243374/> 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