

**K153137 HemosIL HIT-Ab(PF4-H), HemosIL HIT-Ab(PF4-H)
Controls**Jul 8, 2016
252 days to decisionK153137 · Product code: **LCO** · Hematology
Source: <https://www.510kdatabase.net/k153137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Platelet Factor 4 Radioimmunoassay (LCO)
Date received	Oct 30, 2015
Decision date	Jul 8, 2016
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	Carol Marble
510(k) history	321 submissions · 320 cleared · 1976-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153137/>. Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026