

K253957 HemosIL Silica Clotting TimeJan 9, 2026
30 days to decisionK253957 · Product code: **GFO** · Hematology
Source: <https://www.510kdatabase.net/k253957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Dec 10, 2025
Decision date	Jan 9, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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