

K251968 HemosIL Fibrinogen-CJul 24, 2025
28 days to decisionK251968 · Product code: **KQJ** · Hematology
Source: <https://www.510kdatabase.net/k251968/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Jun 26, 2025
Decision date	Jul 24, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	HemosIL Fibrinogen-C XL

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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