

**K221359 ACL TOP 970 CL, HemosIL CL Anti-Cardiolipin IgM,
HemosIL CL Anti-β2 Glycoprotein-I IgM**Sep 29, 2023
506 days to decisionK221359 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k221359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	May 11, 2022
Decision date	Sep 29, 2023
Days to decision	506 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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