

K040359 HEMOSIL SPECIAL TEST CONTROLS LEVEL 1 & 2Mar 19, 2004
35 days to decisionK040359 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k040359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 13, 2004
Decision date	Mar 19, 2004
Days to decision	35 days
Third-party review	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/k040359/> 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 June 10, 2026