

K043459 HEMOSIL FACTOR XII DEFICIENT PLASMAFeb 9, 2005
56 days to decisionK043459 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k043459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Dec 15, 2004
Decision date	Feb 9, 2005
Days to decision	56 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

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