

**K050661 HEMOSIL FACTOR II DEFICIENT PLASMA**May 2, 2005  
48 days to decisionK050661 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k050661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Mar 15, 2005
Decision date	May 2, 2005
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentation Laboratory CO</b>
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

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