

**K042576 COATEST SP FVIII**Dec 2, 2004  
71 days to decisionK042576 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k042576/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Sep 22, 2004
Decision date	Dec 2, 2004
Days to decision	71 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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