

K033631 MODIFICATION TO COATEST FACTOR VIIIDec 15, 2003
26 days to decisionK033631 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k033631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 19, 2003
Decision date	Dec 15, 2003
Days to decision	26 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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