

K082205 FACTOR VIII ANTIBODY SCREENNov 20, 2008
107 days to decisionK082205 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k082205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 5, 2008
Decision date	Nov 20, 2008
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genetic Testing Institute
Location	Mchenry, IL, US
Contact	MICHELLE A STAPLETON
510(k) history	6 submissions · 6 cleared · 1984-2008

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