

K052825 VISULIZE FACTOR VIII ANTIGEN KIT, MODEL FVIII-AG

Jan 20, 2006
107 days to decision

K052825 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k052825/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Oct 5, 2005
Decision date	Jan 20, 2006
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Affinity Biologicals, Inc.
Location	Ancaster, Ontario, CA
Contact	DENISE FOULON
510(k) history	5 submissions · 5 cleared · 2005-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k052825/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026