

K110432 VISUCON-F FROZEN COAG SCREEN N, VISUCON-F FROZEN COAG SCREEN ABNOct 20, 2011
247 days to decisionK110432 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k110432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Feb 15, 2011
Decision date	Oct 20, 2011
Days to decision	247 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

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