

**K091284 VISUCAL-F FROZEN CALIBRATOR PLASMA AND VISUCON-F FROZEN NORMAL AND ABNORMAL CONTROL PLASMA**

Oct 28, 2009  
180 days to decision

K091284 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k091284/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	May 1, 2009
Decision date	Oct 28, 2009
Days to decision	180 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k091284/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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