

K150144 VisuCon-F Low Fibrinogen Control PlasmaMar 6, 2016
409 days to decisionK150144 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k150144/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plasma, Coagulation Control (GGN) |
| Date received | Jan 22, 2015 |
| Decision date | Mar 6, 2016 |
| Days to decision | 409 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.netDevice record: <https://www.510kdatabase.net/k150144/> 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