

**K043451 BIOPHEN NORMAL AND ABNORMAL CONTROL  
PLASMA**Mar 17, 2005  
93 days to decisionK043451 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k043451/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Plasma, Coagulation Control (GGN)
Date received	Dec 14, 2004
Decision date	Mar 17, 2005
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary
Other names	BIOPHEN PLASMA CALIBRATOR

**APPLICANT**

---

Company	<b>Hyphen Biomed</b>
Location	Mason, OH, US
Contact	OLA ANDERSON
510(k) history	6 submissions · 6 cleared · 2005-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043451/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 27, 2026