

**K051472 BIOPHEN LMWH CONTROL, LMWH CONTROL LOW,  
UFH CONTROL, HEPARIN CALIBRATOR & UFH CALIBRATOR**Dec 23, 2005  
203 days to decisionK051472 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k051472/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Jun 3, 2005
Decision date	Dec 23, 2005
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051472/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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