

K043007 BIOPHEN ANTITHROMBIN 2.5, REFERENCE # 221102Nov 7, 2005
371 days to decisionK043007 · Product code: **JBQ** · Hematology
Source: <https://www.510kdatabase.net/k043007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antithrombin Iii Quantitation (JBQ)
Date received	Nov 1, 2004
Decision date	Nov 7, 2005
Days to decision	371 days
Third-party review	No
Summary / Statement	Summary
Other names	BIOPHEN ANTITHROMBIN 5, REFERENCE # 221105

APPLICANT

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

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