

**K083729 HEMOCLOT QUANTI- V-L, FACTOR V-L CALIBRATOR,
BIOPHEN V-L CAL (UNDILUTED), BIOPHEN ACT. PC-R
CONTROL PLASMA AND BIOPHEN**May 8, 2009
143 days to decisionK083729 · Product code: **GGW** · Hematology
Source: <https://www.510kdatabase.net/k083729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Dec 16, 2008
Decision date	May 8, 2009
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aniara Diagnostica, LLC
Location	Mason, OH, US
Contact	OLA ANDERSON
510(k) history	1 submissions · 1 cleared · 2009-2009

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