

**K050799 TRIAGE(R) D-DIMER CALIBRATION VERIFICATION CONTROLS**Jun 29, 2005  
91 days to decisionK050799 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k050799/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Mar 30, 2005
Decision date	Jun 29, 2005
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary
Other names	TRIAGE(R) D-DIMER CONTROLS

**APPLICANT**

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Company	<b>Biosite Incorporated</b>
Location	San Diego, CA, US
Contact	RACHAEL S WILLIAMSON
510(k) history	46 submissions · 45 cleared · 1990-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050799/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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