

**K061803 STA - CONTROL LA 1+2**Jul 28, 2006  
31 days to decisionK061803 · Product code: **GGC** · Hematology  
Source: <https://www.510kdatabase.net/k061803/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Jun 27, 2006
Decision date	Jul 28, 2006
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diagnostica Stago, Inc.</b>
Location	Parsippany, NJ, US
Contact	LAURA WORFOLK
Website	<a href="https://www.stago-us.com">https://www.stago-us.com</a>
510(k) history	16 submissions · 16 cleared · 2001-2026

Diagnostica Stago, Inc. is an industry leader in hemostasis and thrombosis analysis. The company provides coagulation instruments, reagent kits, and related systems for clinical and research laboratories. With a manufacturing facility in Parsippany, US, the company has served the hemostasis laboratory community for over 25 years. Diagnostica Stago, Inc. has received FDA 510(k) clearances from total submissions since 2001. All submissions focus on Hematology devices. The company's latest clearance in 2026 demonstrates continued innovation and active regulatory engagement i...

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