

**K053111 STA-CEPHASCREEN KIT**May 4, 2006  
181 days to decisionK053111 · Product code: **GFO** · Hematology  
Source: <https://www.510kdatabase.net/k053111/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Nov 4, 2005
Decision date	May 4, 2006
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diagnostica Stago, Inc.</b>
Location	Parsippany, NJ, US
Contact	JIM BARROW
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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