

K061805 STA - STACLOT DRVV SCREENDec 6, 2006
162 days to decisionK061805 · Product code: **GIR** · Hematology
Source: <https://www.510kdatabase.net/k061805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Russel Viper Venom (GIR)
Date received	Jun 27, 2006
Decision date	Dec 6, 2006
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary
Other names	STA - STACLOT DRVV CONFIRM

APPLICANT

Company	Diagnostica Stago, Inc.
Location	Parsippany, NJ, US
Contact	LAURA WORFOLK
Website	https://www.stago-us.com
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...
