

K093167 STA COMPACT AUTOMATED MULTI-PARAMETRIC ANALYZERDec 22, 2009
76 days to decisionK093167 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k093167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Oct 7, 2009
Decision date	Dec 22, 2009
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostica Stago, Inc.
Location	Parsippany, NJ, US
Contact	UMBERTO V PARROTTA
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...

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Device record: <https://www.510kdatabase.net/k093167/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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