

K082675 STA-R EVOLUTION AUTOMATED MULTI-PARAMETRIC ANALYZEROct 10, 2008
25 days to decisionK082675 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k082675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Sep 15, 2008
Decision date	Oct 10, 2008
Days to decision	25 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...