

K010350 STA -CALIBRATOR HBPM/LMWH KITApr 9, 2001
63 days to decisionK010350 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k010350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Feb 5, 2001
Decision date	Apr 9, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostica Stago, Inc.
Location	Parsippany, NJ, US
Contact	ANDREW LOC B. LE
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...
