FDA 510(k) Premarket Notification

CLEARED

K111822 STA(R) - LIQUID ANTI-XA, MULTI HEP CALIBRATOR, QUALITY HNF / UFH, QUALITY HBPM / LMWH

Oct 26, 2011
120 days to decision

K111822 · Product code: **KFF** · Hematology
Source: https://www.510kdatabase.net/k111822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jun 28, 2011
Decision date	Oct 26, 2011
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostica Stago, Inc.**
Location	Parsippany, NJ, US
Contact	CARLO D'ALESSANDRO
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...