FDA 510(k) Premarket Notification

K253658 STA Satellite Max®

CLEARED

Apr 27, 2026
158 days to decision

K253658 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k253658/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Nov 20, 2025
Decision date	Apr 27, 2026
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostica Stago, Inc.**
Location	Parsippany, NJ, US
Contact	Louise Sigismondi
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...