

K212183 STA R Max 3, STA Compact Max 3Jun 7, 2023
694 days to decisionK212183 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k212183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 13, 2021
Decision date	Jun 7, 2023
Days to decision	694 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diagnostica Stago S.A.S
Location	Gennevilliers, FR
Contact	Pauline Vasselon
510(k) history	3 submissions · 3 cleared · 2015-2023

REGULATORY CONSULTANT

Consulting firm	Diagnostica Stago, Inc.
Contact	Anthony Dennis

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026