

**K151964 Xprecia Stride Coagulation System, Xprecia System
PT Controls**

Sep 30, 2016
442 days to decision

K151964 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k151964/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jul 16, 2015
Decision date	Sep 30, 2016
Days to decision	442 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	NOOR MALKI
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151964/>. 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 13, 2026