

K230802 Xprecia Prime Coagulation SystemMar 15, 2024
358 days to decisionK230802 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k230802/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Test, Time, Prothrombin (GJS)
Date received	Mar 23, 2023
Decision date	Mar 15, 2024
Days to decision	358 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Universal Biosensors Pty, Ltd.
Location	Rowville, AU
Contact	Nosheen Hameed
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230802/> 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