

K022922 HARMONY INR MONITORING SYSTEMSep 30, 2002
26 days to decisionK022922 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k022922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Time, Prothrombin (GJS)
Date received	Sep 4, 2002
Decision date	Sep 30, 2002
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lifescan, Inc.
Location	Mchenry, IL, US
Contact	JOHN E HUGHES
510(k) history	42 submissions · 42 cleared · 1981-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022922/> 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 June 8, 2026