

K972796 SIGMA DIAGNOSTICS THROMBOMAX WITH CALCIUMOct 10, 1997
74 days to decisionK972796 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k972796/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jul 28, 1997
Decision date	Oct 10, 1997
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972796/> 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 14, 2026