

**K982209 ACCUCLOT THROMBIN TIME REAGENT MODEL
A8713/A4589**Oct 15, 1998
114 days to decisionK982209 · Product code: **GJA** · Hematology
Source: <https://www.510kdatabase.net/k982209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Thrombin Time (GJA)
Date received	Jun 23, 1998
Decision date	Oct 15, 1998
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982209/> 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