

K974343 DADE INNOVINJul 22, 1998
245 days to decisionK974343 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k974343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Nov 19, 1997
Decision date	Jul 22, 1998
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Intl., Inc.
Location	Deerfield, IL, US
Contact	RADAMES RIESGO
510(k) history	30 submissions · 30 cleared · 1995-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974343/> 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 28, 2026