

K863594 ACTIN FSL ACTIVATED PTT REAGENTOct 17, 1986
32 days to decisionK863594 · Product code: **GGW** · Hematology
Source: <https://www.510kdatabase.net/k863594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Sep 15, 1986
Decision date	Oct 17, 1986
Days to decision	32 days
Third-party review	No

APPLICANT

Company	American Dade
Location	Mchenry, IL, US
Contact	KAREN H DARCY
510(k) history	149 submissions · 149 cleared · 1980-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863594/>; 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