

K853986 THROMBOPLASTIN-R REAGENTNov 12, 1985
46 days to decisionK853986 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k853986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Sep 27, 1985
Decision date	Nov 12, 1985
Days to decision	46 days
Third-party review	No

APPLICANT

Company	American Dade
Location	Mchenry, IL, US
Contact	JAMES E KELLER
510(k) history	149 submissions · 149 cleared · 1980-1987

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853986/>; 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