

K891169 DADE THROMBOPLASTIN ISApr 10, 1989
35 days to decisionK891169 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k891169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Mar 6, 1989
Decision date	Apr 10, 1989
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	JEANNE-MARIE VARGA
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891169/>; 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 17, 2026