

K854572 COATEST PLASMINOGENFeb 26, 1986
104 days to decisionK854572 · Product code: **DDX** · Hematology
Source: <https://www.510kdatabase.net/k854572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasminogen, Antigen, Antiserum, Control (DDX)
Date received	Nov 14, 1985
Decision date	Feb 26, 1986
Days to decision	104 days
Third-party review	No

APPLICANT

Company	Kabivitrum, Inc.
Location	Walker, MI, US
Contact	RONALD G LEONARDI
510(k) history	8 submissions · 8 cleared · 1981-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k854572/>, 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 29, 2026