

K880292 FACTOR VIII REFERENCE PLASMAFeb 19, 1988
25 days to decisionK880292 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k880292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jan 25, 1988
Decision date	Feb 19, 1988
Days to decision	25 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	ERIC PETERSEN
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880292/>; 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