

K981709 COAGULATION FACTOR V DEFICIENT PLASMA

Oct 13, 1998
162 days to decision

K981709 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k981709/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	May 4, 1998
Decision date	Oct 13, 1998
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	MARIO A LOWE
510(k) history	343 submissions · 343 cleared · 1978-2010

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Device record: <https://www.510kdatabase.net/k981709/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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