

K912679 DADE(R) IMMUNOADSORBED FACT V DEF PLASMA (HUMAN)

Sep 10, 1991
84 days to decision

K912679 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k912679/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jun 18, 1991
Decision date	Sep 10, 1991
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	NANCY A HORNBAKER
510(k) history	505 submissions · 496 cleared · 1977-2019

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Device record: <https://www.510kdatabase.net/k912679/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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