

**K853461 COAGULATION FACTOR IX DEFICIENT SUBSTRATE  
PLASMA**Aug 29, 1985  
10 days to decisionK853461 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k853461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 19, 1985
Decision date	Aug 29, 1985
Days to decision	10 days
Third-party review	No

**APPLICANT**

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Company	<b>American Dade</b>
Location	Mchenry, IL, US
Contact	JAMES E KELLER
510(k) history	149 submissions · 149 cleared · 1980-1987

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853461/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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