

**K853462 COAGULATION FACTOR VIII DEFICIENT SUBSTRATE
PLASMA**Aug 29, 1985
10 days to decisionK853462 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k853462/>**SUBMISSION DETAILS**

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

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

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