

K820085 DADE FACTOR ASSAY REFERENCE PLASMAFeb 23, 1982
42 days to decisionK820085 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k820085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jan 12, 1982
Decision date	Feb 23, 1982
Days to decision	42 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k820085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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