

K834050 PROTOPATH FACTOR IX ASSAYFeb 4, 1984
73 days to decisionK834050 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k834050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 23, 1983
Decision date	Feb 4, 1984
Days to decision	73 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/k834050/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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