

K792656 HELENA FACTOR XII DEFICIENTJan 24, 1980
29 days to decisionK792656 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k792656/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Dec 26, 1979
Decision date	Jan 24, 1980
Days to decision	29 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

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Device record: <https://www.510kdatabase.net/k792656/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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