

K792475 HELENA FACTOR IX DEFICIENT SUBSTRATEDec 31, 1979
28 days to decisionK792475 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k792475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Dec 3, 1979
Decision date	Dec 31, 1979
Days to decision	28 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/k792475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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