

K792335 HELENA FACTOR VIII DEFICIENT SUB. PLASMADec 4, 1979
15 days to decisionK792335 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k792335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 19, 1979
Decision date	Dec 4, 1979
Days to decision	15 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/k792335/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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