

K823267 FACTOR VIII RELATED ANTIGEN ROCKET EIDDec 28, 1982
56 days to decisionK823267 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k823267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 2, 1982
Decision date	Dec 28, 1982
Days to decision	56 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/k823267/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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