

**K834031 FACTOR II DEFICIENT SUBSTRATE PLASMA**Dec 16, 1983  
24 days to decisionK834031 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k834031/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 22, 1983
Decision date	Dec 16, 1983
Days to decision	24 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k834031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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