

**K792336 HELENA FACTOR II DEFICIENT SUB. PLASMA**Dec 27, 1979  
38 days to decisionK792336 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k792336/>**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 19, 1979
Decision date	Dec 27, 1979
Days to decision	38 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/k792336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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