

K952321 PORCINE FACTOR VIIIMar 11, 1996
298 days to decisionK952321 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k952321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	May 18, 1995
Decision date	Mar 11, 1996
Days to decision	298 days
Third-party review	No
Summary / Statement	Statement
Other names	C REAGENT

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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Device record: <https://www.510kdatabase.net/k952321/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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