

K904247 FREE PROTEIN S REAGENT CAT. NO. 5363Jan 18, 1991
126 days to decisionK904247 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k904247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Sep 14, 1990
Decision date	Jan 18, 1991
Days to decision	126 days
Third-party review	No

APPLICANT

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

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