

K914307 SPECTROLYSE PROTEIN C KITDec 9, 1991
75 days to decisionK914307 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k914307/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Sep 25, 1991
Decision date	Dec 9, 1991
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biopool AB
Location	Ontario, L7I 6b8, CA
Contact	ANDREW L CERSKUS
510(k) history	13 submissions · 12 cleared · 1990-1995

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