

K912025 SPECTROLYSE PLASMINOGEN SK KITAug 22, 1991
107 days to decisionK912025 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k912025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	May 7, 1991
Decision date	Aug 22, 1991
Days to decision	107 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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