

K922782 SPECTROLYSE/PL PAI KITOct 9, 1992
122 days to decisionK922782 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k922782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jun 9, 1992
Decision date	Oct 9, 1992
Days to decision	122 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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