

K971519 ASSERACHROM TPA TEST KITAug 19, 1997
116 days to decisionK971519 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k971519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Apr 25, 1997
Decision date	Aug 19, 1997
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Bioproducts Co.
Location	Parsippany, NJ, US
Contact	ANDREW LOC B LE
510(k) history	79 submissions · 75 cleared · 1985-1998

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