

K974596 DIMERTEST LATEX ASSAYMay 26, 1998
168 days to decisionK974596 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k974596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Dec 9, 1997
Decision date	May 26, 1998
Days to decision	168 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Agen Biomedical , Ltd.
Location	Brisbane, AU
Contact	RUSSELL RICHARDS
510(k) history	6 submissions · 6 cleared · 1988-1999

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