

K945642 AGEN DIMERTEST GOLD EIAOct 25, 1995
343 days to decisionK945642 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k945642/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Nov 16, 1994
Decision date	Oct 25, 1995
Days to decision	343 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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