

K905643 BED RED D-DIMER WHOLE BLOOD AGGLUTINATION ASSAYApr 12, 1991
116 days to decisionK905643 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k905643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Dec 17, 1990
Decision date	Apr 12, 1991
Days to decision	116 days
Third-party review	No

APPLICANT

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

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