

K920147 THROMBIN CLOTTING TIME REAGENTMay 1, 1992
109 days to decisionK920147 · Product code: **GJA** · Hematology
Source: <https://www.510kdatabase.net/k920147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Thrombin Time (GJA)
Date received	Jan 13, 1992
Decision date	May 1, 1992
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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