

K892050 HELENA THROMBOPLASTIN REAGENTJun 7, 1989
70 days to decisionK892050 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k892050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Mar 29, 1989
Decision date	Jun 7, 1989
Days to decision	70 days
Third-party review	No

APPLICANT

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

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