

K940310 HELENA THROMBOPLASTIN-MI REAGENTApr 20, 1994
86 days to decisionK940310 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k940310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jan 24, 1994
Decision date	Apr 20, 1994
Days to decision	86 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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