

**K935169 APTT-ES**Dec 2, 1994  
402 days to decisionK935169 · Product code: **GFO** · Hematology  
Source: <https://www.510kdatabase.net/k935169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Oct 26, 1993
Decision date	Dec 2, 1994
Days to decision	402 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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