

K915418 ELLAGIC ACID APTT REAGENTFeb 14, 1992
74 days to decisionK915418 · Product code: **GFO** · Hematology
Source: <https://www.510kdatabase.net/k915418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Dec 2, 1991
Decision date	Feb 14, 1992
Days to decision	74 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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