

K921465 CAT. NO. 1471 (110V) & CAT. NO. 1472 (220V)Jun 29, 1992
94 days to decisionK921465 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k921465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	Mar 27, 1992
Decision date	Jun 29, 1992
Days to decision	94 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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