

K941737 SPECIALTY ASSAYED CONTROL-1Oct 7, 1994
183 days to decisionK941737 · Product code: **GIZ** · Hematology
Source: <https://www.510kdatabase.net/k941737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Control, Normal (GIZ)
Date received	Apr 7, 1994
Decision date	Oct 7, 1994
Days to decision	183 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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