

K941872 SPECIALTY ASSAYED CONTROL-2 CAT. NO. 5302Nov 21, 1994
217 days to decisionK941872 · Product code: **GGC** · Hematology
Source: <https://www.510kdatabase.net/k941872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Apr 18, 1994
Decision date	Nov 21, 1994
Days to decision	217 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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