

**K941860 SPECIALTY ASSAYED REFERENCE PLASMA
(S.A.R.P.)**

Sep 14, 1994
152 days to decision

K941860 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k941860/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Apr 15, 1994
Decision date	Sep 14, 1994
Days to decision	152 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k941860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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