

K914949 COAGULATION ARPR,CAT.NO.5185Mar 4, 1992
121 days to decisionK914949 · Product code: **GGN** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Nov 4, 1991
Decision date	Mar 4, 1992
Days to decision	121 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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