

K914188 KOAGULAB CTS CHROMOGRNIC TESTING SYSTEMAug 26, 1992
343 days to decisionK914188 · Product code: **JPA** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Sep 18, 1991
Decision date	Aug 26, 1992
Days to decision	343 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
Contact	PATRICK A ROCHE
510(k) history	126 submissions · 126 cleared · 1981-1997

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