

**K983892 COAGUCHEK PRO SYSTEM, APTT TEST
CARTRIDGES FOR COAGUCHEK PRO SYSTEM, APTT
CONTROLS FOR COAGUCHEK PRO SYSTEM, COAGUCHEK P**Apr 13, 1999
161 days to decisionK983892 · 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	Nov 3, 1998
Decision date	Apr 13, 1999
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics/Boehringer Mannheim GmbH
Location	Indianapolis, IN, US
Contact	LUANN OCHS
510(k) history	3 submissions · 3 cleared · 1998-1999

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