

K994349 COAGUCHEK S SYSTEM, MODEL 2138280Sep 6, 2000
258 days to decisionK994349 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k994349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Dec 23, 1999
Decision date	Sep 6, 2000
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	JENNIFER TRIBBETT
510(k) history	264 submissions · 263 cleared · 1999-2013

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