

**K030845 COAGUCHEK PT.S TEST FOR PROTHROMBIN TIME
SELF-TESTING**May 22, 2003
66 days to decisionK030845 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k030845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Mar 17, 2003
Decision date	May 22, 2003
Days to decision	66 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030845/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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