

K033491 ROCHE DIAGNOSTICS CARDIAC D-DIMER RAPID ASSAYSep 1, 2004
302 days to decisionK033491 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k033491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Nov 4, 2003
Decision date	Sep 1, 2004
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary
Other names	ROCHE DIAGNOSTICS CARDIAC D-DIMER CONTROLS

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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