

**K002706 ROCHE DIAGNOSTICS TINA-QUANT D-DIMER ON
COBAS INTEGRA**Mar 16, 2001
198 days to decisionK002706 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k002706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Aug 30, 2000
Decision date	Mar 16, 2001
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary
Other names	ROCHE DIAGNOSTICS TINA-QUANT D-DIMER ON HITACHI

APPLICANT

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

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