

K030740 MODIFICATION TO TINA-QUANT D-DIMER TEST SYSTEMApr 1, 2003
22 days to decisionK030740 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k030740/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fibrin Split Products (GHH)
Date received	Mar 10, 2003
Decision date	Apr 1, 2003
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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