

K011143 TINA-QUANT D-DIMER TEST SYSTEMMay 29, 2001
46 days to decisionK011143 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k011143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fibrin Split Products (GHH)
Date received	Apr 13, 2001
Decision date	May 29, 2001
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026