

**K062203 TINA-QUANT D-DIMER TEST SYSTEM**Mar 14, 2007  
225 days to decisionK062203 · Product code: **GHH** · Hematology  
Source: <https://www.510kdatabase.net/k062203/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Aug 1, 2006
Decision date	Mar 14, 2007
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	THERESA AMBROSE BUSH
510(k) history	264 submissions · 263 cleared · 1999-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062203/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026