

**K012393 TINA-QUANT TRANSFERRIN VER.2**Sep 19, 2001  
54 days to decisionK012393 · Product code: **DDG** · Immunology  
Source: <https://www.510kdatabase.net/k012393/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transferrin, Antigen, Antiserum, Control (DDG)
Date received	Jul 27, 2001
Decision date	Sep 19, 2001
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012393/> 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