

**K003064 TINA-QUANT SOLUBLE TRANSFERRIN RECEPTOR  
TEST SYSTEM, HITACHI CATALOG # 2148315**May 1, 2001  
211 days to decisionK003064 · Product code: **DDG** · Immunology  
Source: <https://www.510kdatabase.net/k003064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transferrin, Antigen, Antiserum, Control (DDG)
Date received	Oct 2, 2000
Decision date	May 1, 2001
Days to decision	211 days
Third-party review	No
Summary / Statement	Statement
Other names	INTEGRA CATALOG # 2148323

**APPLICANT**

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

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