

**K053603 C-REACTIVE PROTEIN (LATEX) HIGH SENSITIVE  
TEST SYSTEM FOR COBAS INTEGRA INSTRUMENTS**Feb 9, 2006  
48 days to decisionK053603 · Product code: **NQD** · Chemistry  
Source: <https://www.510kdatabase.net/k053603/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD)
Date received	Dec 23, 2005
Decision date	Feb 9, 2006
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053603/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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