

**K063543 COBAS INTEGRA BILIRUBIN SPECIAL AND  
ROCHE/HITACHI BILRUBIN TOTAL, MODELS 20737496 322,  
03261638 190, AND 11822713 226**Dec 22, 2006  
28 days to decisionK063543 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k063543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Nov 24, 2006
Decision date	Dec 22, 2006
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	CORINA HARPER
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/k063543/>; 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