

**K981632 ROCHE DIAGNOSTICS, BOEHRINGER MANNHEIM
LIQUID TOTAL BILIRUBIN REAGENT**Jun 15, 1998
38 days to decisionK981632 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k981632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	May 8, 1998
Decision date	Jun 15, 1998
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics/Boehringer Mannheim GmbH
Location	Indianapolis, IN, US
Contact	LUANN OCHS
510(k) history	3 submissions · 3 cleared · 1998-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981632/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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