

K040174 BILIRUBIN ASSAY ON THE OMNI S ANALYZERMay 14, 2004
109 days to decisionK040174 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k040174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Jan 26, 2004
Decision date	May 14, 2004
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	JENNIFER TRIBBETT
510(k) history	264 submissions · 263 cleared · 1999-2013

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