

**K110277 RAPIDPOINT 405 NEONATAL BILIRUBIN**Aug 15, 2011  
196 days to decisionK110277 · Product code: **MQM** · Chemistry  
Source: <https://www.510kdatabase.net/k110277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Jan 31, 2011
Decision date	Aug 15, 2011
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	Steven Goldberg
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110277/> 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 May 28, 2026