

**K980646 IL SYNTHESIS--ADDITION OF BILIRUBIN AS A MEASURED PARAMETER FOR NEONATE WHOLE BLOOD SAMPLES**May 6, 1998  
76 days to decisionK980646 · Product code: **MQM** · Chemistry  
Source: <https://www.510kdatabase.net/k980646/>**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	Feb 19, 1998
Decision date	May 6, 1998
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentation Laboratory CO</b>
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

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