

K994438 BILICHEK NON-INVASIVE BILIRUBIN ANALYZERFeb 4, 2000
36 days to decisionK994438 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k994438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Dec 30, 1999
Decision date	Feb 4, 2000
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spectrx, Inc.
Location	Norcross, GA, US
Contact	JAMES R VEALE
510(k) history	2 submissions · 2 cleared · 2000-2005

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