

K063845 ADVIA CHEMISTRY TOTAL BILIRUBIN_2Dec 7, 2007
345 days to decisionK063845 · Product code: **JFM** · Chemistry
Source: <https://www.510kdatabase.net/k063845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Dec 27, 2006
Decision date	Dec 7, 2007
Days to decision	345 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	PHILIP LIU
510(k) history	46 submissions · 46 cleared · 2003-2018

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