

**K053131 WAKO TOTAL BILIRUBIN V, MODELS 410-22701,  
998-23291, 416-22801, 990-23191**Dec 30, 2005  
52 days to decisionK053131 · Product code: JFM · Chemistry  
Source: <https://www.510kdatabase.net/k053131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Nov 8, 2005
Decision date	Dec 30, 2005
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wako Chemicals USA, Inc.</b>
Location	Mchenry, IL, US
Contact	LORI CREASY
510(k) history	124 submissions · 123 cleared · 1981-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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