

**K053132 WAKO DIRECT BILIRUBIN V, MODELS 996-23591,
412-22901, 992-23691, 998-23791**Dec 30, 2005
52 days to decisionK053132 · Product code: JFM · Chemistry
Source: <https://www.510kdatabase.net/k053132/>**SUBMISSION DETAILS**

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

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

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