

**K970986 WAKO DIRECT BILIRUBIN V**May 7, 1997  
50 days to decisionK970986 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k970986/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Mar 18, 1997
Decision date	May 7, 1997
Days to decision	50 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	TONYA MALLORY
510(k) history	124 submissions · 123 cleared · 1981-2011

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