

**K954145 WAKO AUTOKIT CH50**Dec 18, 1995  
104 days to decisionK954145 · Product code: **DAE** · Immunology  
Source: <https://www.510kdatabase.net/k954145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C9, Antigen, Antiserum, Control (DAE)
Date received	Sep 5, 1995
Decision date	Dec 18, 1995
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

**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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