

**K010332 WAKO IMMUNOASSAY CALIBRATOR SET**Aug 1, 2001  
180 days to decisionK010332 · Product code: **JIT** · Immunology  
Source: <https://www.510kdatabase.net/k010332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Feb 2, 2001
Decision date	Aug 1, 2001
Days to decision	180 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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