

K010325 WAKO AUTOKIT C4Jun 25, 2001
143 days to decisionK010325 · Product code: **DBI** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C4, Antigen, Antiserum, Control (DBI)
Date received	Feb 2, 2001
Decision date	Jun 25, 2001
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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