

K001921 WAKO AUTOKIT LP(A)/EXPRESS 550Jul 23, 2000
30 days to decisionK001921 · Product code: **DFC** · Immunology
Source: <https://www.510kdatabase.net/k001921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Jun 23, 2000
Decision date	Jul 23, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

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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