

**K001931 WAKO AUTOKIT LP(A) & LP(A)
CALIBRATOR/AEROSSET**Jul 24, 2000
28 days to decisionK001931 · Product code: **DFC** · Immunology
Source: <https://www.510kdatabase.net/k001931/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Jun 26, 2000
Decision date	Jul 24, 2000
Days to decision	28 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001931/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026