

**K001929 WAKO AUTOKIT LP(A) AND LP(A)  
CALIBRATOR/COBAS FARA**Jul 24, 2000  
28 days to decisionK001929 · Product code: **DFC** · Chemistry  
Source: <https://www.510kdatabase.net/k001929/>**SUBMISSION DETAILS**

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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**

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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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001929/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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