

**K040226 WAKO AUTO KIT PREALBUMIN, WAKO AUTOKIT
PREALBUMIN CALIBRATOR SET, PREALBUMIN CONTROL
SET**Mar 25, 2004
52 days to decisionK040226 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k040226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Feb 2, 2004
Decision date	Mar 25, 2004
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040226/> 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