

**K030320 WAKO AUTOKIT MICRO ALBUMIN, WAKO AUTOKIT  
MICRO CALIBRATOR SET, MICRO ALBUMIN CONTROL SET**Apr 11, 2003  
71 days to decisionK030320 · Product code: **JIS** · Chemistry  
Source: <https://www.510kdatabase.net/k030320/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Primary (JIS)
Date received	Jan 30, 2003
Decision date	Apr 11, 2003
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030320/> 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