

**K001005 WAKO HDL-C/LDL-C CALIBRATOR**Jun 1, 2000  
64 days to decisionK001005 · Product code: **JIS** · Chemistry  
Source: <https://www.510kdatabase.net/k001005/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Primary (JIS)
Date received	Mar 29, 2000
Decision date	Jun 1, 2000
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001005/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026