

K880803 WAKO(TM) IGA-HA DIRECTMar 29, 1988
29 days to decisionK880803 · Product code: **CZP** · Immunology
Source: <https://www.510kdatabase.net/k880803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Iga, Antigen, Antiserum, Control (CZP)
Date received	Feb 29, 1988
Decision date	Mar 29, 1988
Days to decision	29 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k880803/>; 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