

**K880828 WAKO(TM) IGM-HA DIRECT**Mar 25, 1988  
24 days to decisionK880828 · Product code: **DFT** · Immunology  
Source: <https://www.510kdatabase.net/k880828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igm, Antigen, Antiserum, Control (DFT)
Date received	Mar 1, 1988
Decision date	Mar 25, 1988
Days to decision	24 days
Third-party review	No

**APPLICANT**

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Company	<b>Wako Chemicals USA, Inc.</b>
Location	Mchenry, IL, US
Contact	TOSHIHIKO ODA
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/k880828/>; 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