

**K062368 WAKO LBA DCP TEST SYSTEM, MODEL 993-05301**Jan 31, 2007  
170 days to decisionK062368 · Product code: **OAU** · Immunology  
Source: <https://www.510kdatabase.net/k062368/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Des-gamma-carboxy-prothrombin (dcp), Risk Assessment, Hepatocellular Carcinoma (OAU)
Date received	Aug 14, 2006
Decision date	Jan 31, 2007
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary
Other names	DCP CONTROL SET, MODEL 995-0551; DCP CALIBRATOR SET, LIBASYS, MODEL 999-05401

**APPLICANT**

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Company	<b>Wako Chemicals USA, Inc.</b>
Location	Mchenry, IL, US
Contact	LORI CREASY
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/k062368/> 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