

**K072393 ELIA DSDNA IMMUNOASSAY, MODEL 14-5500-01,  
ELIA ANA CONTROL, MODEL 83-1004-01**Dec 7, 2007  
102 days to decisionK072393 · Product code: **LSW** · Immunology  
Source: <https://www.510kdatabase.net/k072393/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody, Antigen And Control (LSW)
Date received	Aug 27, 2007
Decision date	Dec 7, 2007
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phadia US, Inc.</b>
Location	Portae, MI, US
Contact	MARTIN R MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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