

**K083188 VARELISA RECOMBI ANA SCREEN, MODEL 12 596**Mar 13, 2009  
135 days to decisionK083188 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k083188/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 29, 2008
Decision date	Mar 13, 2009
Days to decision	135 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/k083188/> 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