

**K083053 EUROIMMUN ANTI-GLIADIN (GAF-3X) ELISA (IGG)**Aug 7, 2009  
297 days to decisionK083053 · Product code: **MST** · Immunology  
Source: <https://www.510kdatabase.net/k083053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Oct 14, 2008
Decision date	Aug 7, 2009
Days to decision	297 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Euroimmun Us, Inc.</b>
Location	Morristown, NJ, US
Contact	KATHRYN KOHL
510(k) history	19 submissions · 19 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083053/> 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 June 19, 2026