

K083052 EUROIMMUN ANTI-GLIADIN (GAF-3X) ELISA (IGA)Jul 28, 2009
287 days to decisionK083052 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k083052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Oct 14, 2008
Decision date	Jul 28, 2009
Days to decision	287 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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