

**K093459 ELIA GLIADIN DP IGA IMMUNOASSAY AND ELIA
GLIADIN DP IGG IMMUNOASSAY, MODELS 14-5538-01,
14-5539-01**Aug 13, 2010
280 days to decisionK093459 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k093459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Nov 6, 2009
Decision date	Aug 13, 2010
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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