

K113377 GLIADIN IGA AND GLIADIN LGADec 14, 2012
394 days to decisionK113377 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k113377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Nov 16, 2011
Decision date	Dec 14, 2012
Days to decision	394 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Grifols USA, LLC
Location	Los Angeles, CA, US
Contact	CATHERINE L WONG
510(k) history	2 submissions · 2 cleared · 2012-2012

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