

K012797 DIAMEDIX IS-ANTI-GLIADIN IGA TEST SYSTEMSep 28, 2001
38 days to decisionK012797 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k012797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Aug 21, 2001
Decision date	Sep 28, 2001
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diamedix Corp.
Location	Miami, FL, US
Contact	LYNNE STIRLING
510(k) history	68 submissions · 68 cleared · 1986-2011

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