

**K002169 GLIADIN IGA ANTIBODY EIA DETECTION SYSTEM**Oct 19, 2000  
93 days to decisionK002169 · Product code: **MST** · Immunology  
Source: <https://www.510kdatabase.net/k002169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Jul 18, 2000
Decision date	Oct 19, 2000
Days to decision	93 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Scimedx Corp.</b>
Location	Denvill, NJ, US
Contact	Gary Lehnus
510(k) history	14 submissions · 14 cleared · 1996-2001

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