

K002189 GLIADIN IGG ANTIBODY EIA DETECTION SYSTEMOct 19, 2000
92 days to decisionK002189 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k002189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Jul 19, 2000
Decision date	Oct 19, 2000
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Scimedx Corp.
Location	Denvill, NJ, US
Contact	GARY L EHNUS
510(k) history	14 submissions · 14 cleared · 1996-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002189/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026