

K964985 QUANTA LITE IGG GLIADIN ELISAMay 30, 1997
168 days to decisionK964985 · Product code: **MST** · Immunology
Source: <https://www.510kdatabase.net/k964985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	Dec 13, 1996
Decision date	May 30, 1997
Days to decision	168 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Inova Diagnostics, Inc.
Location	San Diego, CA, US
Contact	BRYSC MYERS
Website	https://www.inovadx.com
510(k) history	138 submissions · 136 cleared · 1988-2026

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...
