

K971441 QUANTA LITE TOXOPLASMA IGGDec 2, 1997
228 days to decisionK971441 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k971441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Apr 18, 1997
Decision date	Dec 2, 1997
Days to decision	228 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Inova Diagnostics, Inc.
Location	San Diego, CA, US
Contact	BRYN C 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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971441/>. 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 28, 2026