

K971672 SERAQUEST TOXOPLASMA IGMOct 21, 1997
167 days to decisionK971672 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k971672/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	May 7, 1997
Decision date	Oct 21, 1997
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quest Intl., Inc.
Location	Fort Smith, AR, US
Contact	ROBERT A CORT
510(k) history	25 submissions · 25 cleared · 1989-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971672/> 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 23, 2026