

K944867 TOXOSTATMay 14, 1996
595 days to decisionK944867 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k944867/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Sep 27, 1994
Decision date	May 14, 1996
Days to decision	595 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bio-Whittaker, Inc., A Cambrex Co.
Location	Walkersville, MD, US
Contact	LEIF E OLSEN
510(k) history	3 submissions · 3 cleared · 1995-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944867/> 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