

**K913467 TOXOGEN**Jan 11, 1993  
525 days to decisionK913467 · Product code: **LLA** · Microbiology  
Source: <https://www.510kdatabase.net/k913467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Direct Agglutination Test, Toxoplasma Gondii (LLA)
Date received	Aug 5, 1991
Decision date	Jan 11, 1993
Days to decision	525 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biokit USA, Inc.</b>
Location	Mchenry, IL, US
Contact	ODRIOZOLA
510(k) history	16 submissions · 16 cleared · 1984-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913467/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026