

**K974261 ACCURUN 135 TOXOPLASMA IGG POSITIVE CONTROL**Dec 11, 1997  
28 days to decisionK974261 · Product code: **LJK** · Microbiology  
Source: <https://www.510kdatabase.net/k974261/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, If, Toxoplasma Gondii (LJK)
Date received	Nov 13, 1997
Decision date	Dec 11, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Boston Biomedica, Inc.</b>
Location	West Bridgewater, MA, US
Contact	PATRICIA E GARRETT
510(k) history	12 submissions · 12 cleared · 1997-2003

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974261/> 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