

**K963297 INCSTAR TOXOPLASMA IGG FAST ELISA ASSAY  
(CAT.#7560)**

Dec 16, 1996  
117 days to decision

K963297 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k963297/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Aug 21, 1996
Decision date	Dec 16, 1996
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Incstar Corp.</b>
Location	Stillwater, MN, US
Contact	MARY FRICK
510(k) history	58 submissions · 57 cleared · 1987-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k963297/>; 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 29, 2026