

**K963296 INCSTAR TOXOPLASMA IGG ALISA ASSAY  
(CAT.#7565)**Dec 16, 1996  
117 days to decisionK963296 · Product code: **LGD** · Microbiology  
Source: <https://www.510kdatabase.net/k963296/>**SUBMISSION DETAILS**

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|-----------------------|--|
| 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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963296/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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