

K963289 INCSTAR TOXOPLASMA IGM CAPTURE ELISA ASSAYMay 1, 1997
253 days to decisionK963289 · Product code: **LGD** · Microbiology
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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	May 1, 1997
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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