

**K955360 INCSTAR CYTOMEGALOVIRUS IGG FAST ELISA
ASSAY**Jul 22, 1996
243 days to decisionK955360 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k955360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Nov 22, 1995
Decision date	Jul 22, 1996
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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