

**K960434 INCSTAR CYTOMEGALOVIRUS IGM CAPTURE ELISA
ASSAY MODEL 8530**Oct 17, 1996
260 days to decisionK960434 · Product code: LFZ · Microbiology
Source: <https://www.510kdatabase.net/k960434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Jan 31, 1996
Decision date	Oct 17, 1996
Days to decision	260 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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