

K921628 EPSTEIN-BARR VIR EARLY ANTI DIFF IGG CLIN-ELISASep 14, 1992
161 days to decisionK921628 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k921628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Apr 6, 1992
Decision date	Sep 14, 1992
Days to decision	161 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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