

K946157 INCSTAR EPSTEIN-BARR VIRAL CAPSID ANTIGEN (VCA) LGM ELISA KIT

Jun 7, 1995
181 days to decision

K946157 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k946157/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Dec 8, 1994
Decision date	Jun 7, 1995
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k946157/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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