

**K992587 EPSTEIN-BARR VIRUS EARLY ANTIGEN (EBV-EA)
IGG IFA TEST SYSTEM**Dec 22, 1999
142 days to decisionK992587 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k992587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Aug 2, 1999
Decision date	Dec 22, 1999
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stellar Bio Systems, Inc.
Location	Columbia, MD, US
Contact	JOHN BREWER
510(k) history	7 submissions · 7 cleared · 1988-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992587/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026