

K973123 EA-D IGG ELISA TEST SYSTEMMar 26, 1998
218 days to decisionK973123 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k973123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Aug 20, 1997
Decision date	Mar 26, 1998
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clark Laboratories, Inc.
Location	Blairstown, NJ, US
Contact	WILLIAM L BOTELER
510(k) history	14 submissions · 14 cleared · 1992-1998

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