

K991660 COPALIS MULTIPLEX EBV ANTIBODY ASSAYJun 4, 1999
21 days to decisionK991660 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k991660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	May 14, 1999
Decision date	Jun 4, 1999
Days to decision	21 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	JUDITH J SMITH
510(k) history	71 submissions · 70 cleared · 1998-2026

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