

K991459 COPALIS EBV-M ANTIBODY ASSAYMay 14, 1999
18 days to decisionK991459 · Product code: **LJN** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibody Igm, If, Epstein-barr Virus (LJN)
Date received	Apr 26, 1999
Decision date	May 14, 1999
Days to decision	18 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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