

K982027 MODIFICATION TO COPALIS CMV TOTAL ANTIBODY ASSAYNov 25, 1998
176 days to decisionK982027 · Product code: **LFZ** · Microbiology
Source: <https://www.510kdatabase.net/k982027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Jun 2, 1998
Decision date	Nov 25, 1998
Days to decision	176 days
Third-party review	No
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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