

K955799 COPALIS CMV TOTAL ANTIBODY ASSAYJul 10, 1996
201 days to decisionK955799 · Product code: **LJO** · Microbiology
Source: <https://www.510kdatabase.net/k955799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Iha, Cytomegalovirus (LJO)
Date received	Dec 22, 1995
Decision date	Jul 10, 1996
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sienna Biotech, Inc.
Location	Bethesda, MD, US
Contact	JOYCE T DAVID
510(k) history	3 submissions · 3 cleared · 1996-1997

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