

K974901 HYBRID CAPTURE SYSTEM CMV DNA ASSAYSep 29, 1998
272 days to decisionK974901 · Product code: **LJO** · Microbiology
Source: <https://www.510kdatabase.net/k974901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Iha, Cytomegalovirus (LJO)
Date received	Dec 31, 1997
Decision date	Sep 29, 1998
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Digene Corp.
Location	Gaithersburg, MD, US
Contact	CONSTANCE A FINCH
510(k) history	9 submissions · 9 cleared · 1997-2001

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