

K921616 CMV-VUE(TM) CMV ANTIGEN DETECTION KITAug 11, 1992
127 days to decisionK921616 · Product code: **LIN** · Microbiology
Source: <https://www.510kdatabase.net/k921616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Antisera, Conjugated Fluorescent, Cytomegalovirus (LIN)
Date received	Apr 6, 1992
Decision date	Aug 11, 1992
Days to decision	127 days
Third-party review	No

APPLICANT

Company	Incstar Corp.
Location	Stillwater, MN, US
Contact	MARY FRICK
510(k) history	58 submissions · 57 cleared · 1987-1997

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