FDA 510(k) Premarket Notification

K951821 CYTOMEGALOVIRUS DIRECT IMMUNOFLUORESCENCE ASSAY

CLEARED

Jun 7, 1996
414 days to decision

K951821 · Product code: **LIN** · Microbiology
Source: https://www.510kdatabase.net/k951821/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Conjugated Fluorescent, Cytomegalovirus (LIN)
Date received	Apr 20, 1995
Decision date	Jun 7, 1996
Days to decision	414 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Light Diagnostics**
Location	Temecula, CA, US
Contact	DALE DEMBROW
510(k) history	19 submissions · 19 cleared · 1993-1999