FDA 510(k) Premarket Notification

K935809 CYTOMEGALOVIRUS INDIRECT IMMUNOFLUORESCENCE ASSAY

CLEARED

May 5, 1994
154 days to decision

K935809 · Product code: **GQH** · Microbiology
Source: https://www.510kdatabase.net/k935809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Cytomegalovirus (GQH)
Date received	Dec 2, 1993
Decision date	May 5, 1994
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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