FDA 510(k) Premarket Notification

K950672 IMMULITE CMV IGG

CLEARED

Jun 17, 1996
490 days to decision

K950672 · Product code: **LFZ** · Microbiology
Source: https://www.510kdatabase.net/k950672/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ)
Date received	Feb 13, 1995
Decision date	Jun 17, 1996
Days to decision	490 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostic Products Corp.**
Location	Mchenry, IL, US
Contact	KEN ASARCH
510(k) history	321 submissions · 321 cleared · 1976-2006