FDA 510(k) Premarket Notification

K951549 EBNA IGG EIA TEST SYSTEM

CLEARED

Apr 29, 1996
391 days to decision

K951549 · Product code: **LLM** · Microbiology
Source: https://www.510kdatabase.net/k951549/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Apr 4, 1995
Decision date	Apr 29, 1996
Days to decision	391 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Immunoprobe, Inc.**
Location	Washington, DC, US
Contact	EDWARD C WILSON, JR.
510(k) history	14 submissions · 14 cleared · 1994-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k951549/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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