FDA 510(k) Premarket Notification

# K954301 ABBOTT CMV TOTAL ANTIBODY EIA (MODIFICATION)

**CLEARED**

Mar 24, 1997
579 days to decision

K954301 · Product code: **LFZ** · Microbiology
Source: https://www.510kdatabase.net/k954301/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Cytomegalovirus (LFZ) |
| Date received | Aug 23, 1995 |
| Decision date | Mar 24, 1997 |
| Days to decision | 579 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Abbott Laboratories** |
| Location | Abbott Park, IL, US |
| Contact | MARY SPIEWAK |
| Website | http://www.abbott.com |
| 510(k) history | 883 submissions · 868 cleared · 1976-2026 |

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...