FDA 510(k) Premarket Notification

# K831535 E.P.T. PLUS TM

**CLEARED**

Jun 30, 1983
48 days to decision

K831535 · Product code: **JHJ** · Chemistry
Source: https://www.510kdatabase.net/k831535/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agglutination Method, Human Chorionic Gonadotropin (JHJ) |
| Date received | May 13, 1983 |
| Decision date | Jun 30, 1983 |
| Days to decision | 48 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Warner-Lambert Co.** |
| Location | Mchenry, IL, US |
| 510(k) history | 50 submissions · 50 cleared · 1979-2003 |