

K864457 CHLAMYSET ANTIBODY EIASep 11, 1987
303 days to decisionK864457 · Product code: **LJC** · Microbiology
Source: <https://www.510kdatabase.net/k864457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, (chlamydiae Group) (LJC)
Date received	Nov 12, 1986
Decision date	Sep 11, 1987
Days to decision	303 days
Third-party review	No

APPLICANT

Company	Orion Corp.
Location	20101 Turku, FL
Contact	TIMO RAINES
510(k) history	21 submissions · 20 cleared · 1985-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864457/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 21, 2026