

K946276 QUICKVUE(R) CHLAMYDIA TESTMay 19, 1995
147 days to decisionK946276 · Product code: **LJC** · Microbiology
Source: <https://www.510kdatabase.net/k946276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, (chlamydiae Group) (LJC)
Date received	Dec 23, 1994
Decision date	May 19, 1995
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quidel Corp.
Location	Washington, DC, US
Contact	Robin Weiner
510(k) history	93 submissions · 93 cleared · 1983-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k946276/> 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 June 8, 2026