

K901975 IPAZYME(TM) CHLAMYDIA TRUE IGM(TM)Mar 8, 1991
311 days to decisionK901975 · Product code: **LKH** · Microbiology
Source: <https://www.510kdatabase.net/k901975/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Immunoperoxidase, Chlamydia Spp. (LKH)
Date received	May 1, 1990
Decision date	Mar 8, 1991
Days to decision	311 days
Third-party review	No

APPLICANT

Company	Savyon Diagnostics , Ltd.
Location	Ashdod, IL
Contact	DR. Y YAKIR
510(k) history	5 submissions · 5 cleared · 1991-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k901975/>; 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 30, 2026