

K904652 LYME STAT M TEST KITOct 21, 1991
371 days to decisionK904652 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k904652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Oct 15, 1990
Decision date	Oct 21, 1991
Days to decision	371 days
Third-party review	No

APPLICANT

Company	Whittaker Bioproducts, Inc.
Location	Walkersville, MD, US
Contact	LEIF E OLSEN
510(k) history	30 submissions · 30 cleared · 1984-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904652/>; 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