

K890281 HUMAN LYME EIA FOR THE DETECT OF ANTIBODIESMar 15, 1989
57 days to decisionK890281 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k890281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jan 17, 1989
Decision date	Mar 15, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

Company	Cambridge Bioscience Corp.
Location	Hopkinton, MA, US
Contact	JACK CASSORLA
510(k) history	5 submissions · 5 cleared · 1985-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k890281/>, 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