

K883487 LYME DISEASE IFA (IGG)Dec 13, 1988
119 days to decisionK883487 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k883487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Aug 16, 1988
Decision date	Dec 13, 1988
Days to decision	119 days
Third-party review	No

APPLICANT

Company	Hillcrest Biologicals
Location	Mchenry, IL, US
Contact	LEE FULLER
510(k) history	33 submissions · 33 cleared · 1983-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883487/>; 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 14, 2026