

K904893 FIAX LYME M TEST KITOct 16, 1991
351 days to decisionK904893 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k904893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Oct 30, 1990
Decision date	Oct 16, 1991
Days to decision	351 days
Third-party review	No

APPLICANT

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

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