

K233367 iDart Lyme IgG ImmunoBlot KitAug 12, 2024
315 days to decisionK233367 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k233367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Oct 2, 2023
Decision date	Aug 12, 2024
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Id-Fish Technology, Inc.
Location	Palo Alto, CA, US
Contact	Jyotsna Shah
510(k) history	3 submissions · 2 cleared · 2017-2025

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