

**K242872 iDart Lyme IgM ImmunoBlot Kit**Jun 12, 2025  
262 days to decisionK242872 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k242872/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Sep 23, 2024
Decision date	Jun 12, 2025
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242872/> 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 13, 2026