

**K242487 Laminar P1 (LDH-HW-001)**Dec 13, 2024  
114 days to decisionK242487 · Product code: **JAF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242487/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Ultrasonic, Nonfetal (JAF)
Date received	Aug 21, 2024
Decision date	Dec 13, 2024
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Laminar Digital Health, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Jess Lee
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>RQM+</b>
Contact	Pierre Bounaud

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242487/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026