FDA 510(k) Premarket Notification

K242487 Laminar P1 (LDH-HW-001)

CLEARED

Dec 13, 2024
114 days to decision

K242487 · 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	**Laminar Digital Health, Inc.**
Location	Sunnyvale, CA, US
Contact	Jess Lee
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Pierre Bounaud

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