

K251494 Eko Foundation Analysis Software with Transformers (EFAST)

Aug 12, 2025
89 days to decision

K251494 · Product code: **DQD** · Cardiovascular
Source: <https://www.510kdatabase.net/k251494/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	May 15, 2025
Decision date	Aug 12, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eko Health, Inc.
Location	Emeryville, CA, US
Contact	Sam Huang
510(k) history	3 submissions · 3 cleared · 2024-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251494/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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