

K233409 Eko Low Ejection Fraction Tool (ELEFT)Mar 28, 2024
174 days to decisionK233409 · Product code: **QYE** · Cardiovascular
Source: <https://www.510kdatabase.net/k233409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced Ejection Fraction Machine Learning-based Notification Software (QYE)
Date received	Oct 6, 2023
Decision date	Mar 28, 2024
Days to decision	174 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.netDevice record: <https://www.510kdatabase.net/k233409/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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