FDA 510(k) Premarket Notification

K213794 Eko Murmur Analysis Software (EMAS)

CLEARED

Jun 29, 2022
205 days to decision

K213794 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k213794/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Dec 6, 2021
Decision date	Jun 29, 2022
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Eko Devices, Inc.**
Location	Berkeley, CA, US
Contact	Sam Huang
510(k) history	6 submissions · 6 cleared · 2015-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k213794/ 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 27, 2026