FDA 510(k) Premarket Notification

K233609 CORE 500 Digital Stethoscope

CLEARED

Mar 28, 2024
136 days to decision

K233609 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k233609/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Nov 13, 2023
Decision date	Mar 28, 2024
Days to decision	136 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