FDA 510(k) Premarket Notification

K230111 CORE 500 Digital Stethoscope

CLEARED

May 26, 2023
129 days to decision

K230111 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k230111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Jan 17, 2023
Decision date	May 26, 2023
Days to decision	129 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, Ph.D.
510(k) history	6 submissions · 6 cleared · 2015-2023