FDA 510(k) Premarket Notification

K212906 HeartBuds Electronic Stethoscope

CLEARED

Mar 14, 2023
547 days to decision

K212906 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k212906/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Sep 13, 2021
Decision date	Mar 14, 2023
Days to decision	547 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Heartbuds, LLC**
Location	Winter Park, FL, US
Contact	Seth Ellis
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**leanRAQA**
Contact	Michelle Lott

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov