

**K212906 HeartBuds Electronic Stethoscope**Mar 14, 2023  
547 days to decisionK212906 · Product code: **DQD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212906/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>leanRAQA</b>
Contact	Michelle Lott

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

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