

**K252915 AiSteth®**May 22, 2026  
252 days to decisionK252915 · Product code: **DQD** · CardiovascularSource: <https://www.510kdatabase.net/k252915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Sep 12, 2025
Decision date	May 22, 2026
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ai Health Highway India Pvt., Ltd.</b>
Location	Bangalore, IN
Contact	Satish S. Jeevannavar
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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