

**K243003 VitalSigns 1-Lead Holter (VSH101)**Jun 17, 2025  
264 days to decisionK243003 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k243003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Sep 26, 2024
Decision date	Jun 17, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>VitalSigns Technology Co., Ltd.</b>
Location	Hsinchu County, TW
Contact	Jih-liang Juang
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243003/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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