

**K232237 Tyto Insights for Wheeze Detection**Dec 13, 2023  
138 days to decisionK232237 · Product code: **PHZ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k232237/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Breath Sound Device (PHZ)
Date received	Jul 28, 2023
Decision date	Dec 13, 2023
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tyto Care , Ltd.</b>
Location	Netanya, IL
Contact	Stella Raizelman Perry
Website	<a href="https://www.tytocare.com">https://www.tytocare.com</a>
510(k) history	9 submissions · 8 cleared · 2016-2026

Tyto Care, Ltd. develops remote clinical examination devices and AI-powered diagnostic solutions for virtual care delivery. The company enables clinicians to conduct comprehensive physical exams from patient homes and community settings, with a manufacturing facility in Netanya, IL. Tyto Care has received FDA 510(k) clearances from total submissions since 2016. The company specializes in respiratory and cardiovascular diagnostic devices, including AI-powered lung sound analysis and digital stethoscope technology. The latest clearance was granted in 2026, confirming active...

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