

K252844 Tyto Insights for Wheeze Detection (with PCCP)Jun 2, 2026
267 days to decisionK252844 · Product code: **PHZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k252844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Breath Sound Device (PHZ)
Date received	Sep 8, 2025
Decision date	Jun 2, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tyto Care , Ltd.
Location	Netanya, IL
Contact	Stella Raizelman Perry
Website	https://www.tytocare.com
510(k) history	10 submissions · 9 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...