FDA 510(k) Premarket Notification

K243567 Tyto Insights for Rhonchi Detection

CLEARED

Apr 7, 2025
140 days to decision

K243567 · Product code: **PHZ** · Anesthesiology
Source: https://www.510kdatabase.net/k243567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Breath Sound Device (PHZ)
Date received	Nov 18, 2024
Decision date	Apr 7, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**Tyto Care , Ltd.**
Location	Netanya, IL
Contact	Stella Raizelman Perry
Website	https://www.tytocare.com
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...

CLINICAL EVIDENCE - NCT06460246

Pulse Oximeter Accuracy During Stable Hypoxia Plateaus

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	12 patients (actual)
Study sites	1 site
Condition studied	Healthy
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 31, 2024
Sponsor	Acurable Ltd. (Industry)

Primary outcome

Performance of the pulse oximeters against corresponding arterial blood oxygen saturation.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06460246