

K240555 Tyto Insights for Crackles DetectionJul 2, 2024
125 days to decisionK240555 · Product code: **PHZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k240555/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Breath Sound Device (PHZ)
Date received	Feb 28, 2024
Decision date	Jul 2, 2024
Days to decision	125 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...