

K221614 TytoCare Lung Sounds Analyzer

Feb 24, 2023
266 days to decisionK221614 · Product code: **PHZ** · Anesthesiology
Source: <https://www.510kdatabase.net/k221614/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Breath Sound Device (PHZ)
Date received	Jun 3, 2022
Decision date	Feb 24, 2023
Days to decision	266 days
Third-party review	No
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...
