

K160401 Tyto StethoscopeOct 19, 2016
250 days to decisionK160401 · Product code: **DQD** · Cardiovascular
Source: <https://www.510kdatabase.net/k160401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Feb 12, 2016
Decision date	Oct 19, 2016
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tyto Care , Ltd.
Location	Netanya, IL
Contact	Yoni Iger
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...
