FDA 510(k) Premarket Notification

K181612 Tyto Stethoscope (OTC)

CLEARED

Dec 17, 2018
181 days to decision

K181612 · Product code: **DQD** · Cardiovascular
Source: https://www.510kdatabase.net/k181612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stethoscope, Electronic (DQD)
Date received	Jun 19, 2018
Decision date	Dec 17, 2018
Days to decision	181 days
Third-party review	Yes
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...

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	DAVE YUNGVIRT

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov