

**K252089 Tyto Stethoscope (G3)**Mar 12, 2026  
253 days to decisionK252089 · Product code: **DQD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252089/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Stethoscope, Electronic (DQD)      |
| Date received         | Jul 2, 2025                        |
| Decision date         | Mar 12, 2026                       |
| Days to decision      | 253 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Tyto Care , Ltd.</b>   |
| Location       | Netanya, IL   |
| Contact        | Stella Raizelman Perry  |
| Website        | <a href="https://www.tytocare.com">https://www.tytocare.com</a> |
| 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...