March 12, 2026

Tyto Care Ltd.
Stella Raizelman Perry
RA&QA Director
14 Beni Gaon Street
Netanya,
Israel

Re: K252089
Trade/Device Name: Tyto Stethoscope (G3)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: February 11, 2026
Received: February 11, 2026

Dear Stella Raizelman Perry:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252089 |

Please provide the device trade name(s).

Tyto Stethoscope (G3)

Please provide your Indications for Use below.

The Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto Stethoscope is intended to be used by lay users in non-clinical environments to capture auscultation sounds for transmission to a clinician for review. The Tyto Stethoscope is for medical diagnostics purposes only. The Tyto Stethoscope is not intended for self-diagnosis.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary

| | |
|---|---|
| **Submitter Name and Address:** | Tyto Care Ltd.<br>14 Beni Gaon Street Netanya, Israel, 4250803 |
| **Contact Person:** | Stella Raizelman Perry RA & QA Director<br>Email: stellar@tytocare.com<br>Phone Number: +972 72-2210750<br>Fax Number: +972 72-2210752 |
| **Establishment Registration Number:** | 3012678246 |
| **Date Prepared:** | March 12, 2026 |
| **Device Trade Name(s):** | Tyto Stethoscope (G3) |
| **Device Common Name:** | Tyto Stethoscope (G3) |
| **Classification:** | **Name:** Electronic Stethoscope<br>**Product code:** DQD<br>**Regulation No:** 21 CFR 870.1875<br>**Class**: II<br>**Panel:** Cardiovascular |

**Primary Predicate Device(s):**

| Device name | 510(k) No. | Date of Clearance |
|---|---|---|
| Tyto Stethoscope (OTC) | K181612 | December 17, 2018 |

**Reference Device(s):**

| Device name | 510(k) No. | Date of Clearance |
|---|---|---|
| eMurmur Heart AI | K220766 | May 31, 2022 |

## Intended use / indication for use statement

The Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto Stethoscope is intended to be used by lay users in non-clinical environments to capture auscultation sounds for transmission to a clinician for review. The Tyto Stethoscope is for medical diagnostics purposes only. The Tyto Stethoscope is not intended for self-diagnosis.

## Device description

The Tyto Stethoscope (G3) system is designed for use by lay users in non-clinical environments to capture auscultation sounds for transmission to a clinician for review. It enables three types of stethoscope exams: Heart, Lungs and Heart Rate.

The Tyto Stethoscope (G3) system is a multiple functions system, the operation process of the system uses four (4) primary functional elements:

**(1)** The Tyto Stethoscope (composed of a TytoCare Device with Stethoscope adaptor supported with proprietary TytoCare Device App software).

The **TytoCare Device App** contains device software functions.

**(2)** A mobile device (e.g., a smartphone, not part of the Tyto Stethoscope device, not supplied by TytoCare, on which the proprietary TytoCare user App is running),

The **TytoCare User App** contains only other software functions.

**(3)** The TytoCare Server platform (composed of server hardware not part of the Tyto Stethoscope device, not supplied by TytoCare, on which the proprietary TytoCare server software is running).

The **TytoCare server software** is composed of two modules:

- TytoCare Server Software (Data Processing Software Module) – contains device software functions
- TytoCare Server Software (Server Management Software Module) – contains other functions

**(4)** A clinician receiving platform located in a clinical environment (e.g., a PC at the clinic, not part of the Tyto Stethoscope device, not supplied by TytoCare, on which the proprietary TytoCare Clinician Dashboard App is running).

**The TytoCare Clinician Dashboard App** is composed of two modules:

- TytoCare Clinician Dashboard (Exam Software Module) – contains device software functions

- TytoCare Clinician Dashboard (Clinician software module) – contains other functions

Two operational flows are optional for using the Tyto Stethoscope (G3): store-and-forward flow and on-line exam flow. Both flows are essentially similar and share the same fundamental steps: performing one or more measurements using the Tyto Stethoscope (G3), sending to a clinician, review of the measurements by the clinician, .While in the store-and-forward flow the user can record the measurements and send the recorded data to the clinician whenever convenient for him/her, an on-line flow may be executed only when also the clinician is available on-line.

*The other functions are not included in the scope of this premarket notification.

**Substantial Equivalence to Predicate Devices**

The following table compares the Tyto Stethoscope (G3) to the predicate device:

| | **Proposed Device** | **Predicate Device** | **Summary** |
|---|---|---|---|
| **Device Name** | Tyto Stethoscope (G3) | Tyto Stethoscope (OTC) | NA |
| **Device Manufacturer** | Tyto Care Ltd. | Tyto Care Ltd. | Same |
| **510(k) Number** | K252089 | K181612 | NA |
| **Classification** | Class II | Class II | Same |
| **Review Panel** | Cardiovascular devices | Cardiovascular devices | Same |
| **Product code** | DQD | DQD | Same |
| **Regulation number** | 21 CFR 870.1875 | 21 CFR 870.1875 | Same |
| **Regulation description** | Electronic Stethoscope | Electronic Stethoscope | Same |
| **Intended use and indication for use** | The Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto Stethoscope is intended to be used by lay users in non-clinical environments to capture auscultation sounds for | The Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto stethoscope is intended for use for patients in all ages by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. | Same<br><br>Proposed device: Recordings captured by lay users.<br>predicate device: recordings captured by lay users and healthcare professionals. Both devices: recordings reviewed by clinicians. The intended use remains the same. |

| | Proposed Device | Predicate Device | Summary |
|---|---|---|---|
| | transmission to a clinician for review. The Tyto Stethoscope is for medical diagnostics purposes only. The Tyto Stethoscope is not intended for self-diagnosis. | | |
| **Type of use** | Over-The-Counter Use | Over-The-Counter Use | Same |
| **Intended patient population** | Intended for patients of all ages | Intended for patients of all ages | Same |
| **Intended user** | lay users (aged 18 or older) capture recordings.<br><br>The recordings are analyzed by healthcare professionals. | Both lay users (18- 65 year sold) and healthcare professionals capture recordings.<br><br>The recordings are analyzed by healthcare professionals | Similar<br><br>For the proposed device, only lay users capture recordings.<br>For both devices, the recordings are analyzed by healthcare professionals. |
| **Intended environment** | Lay users capture recordings in non-clinical settings, clinicians review remotely. | Lay users and Healthcare professionals capture recordings in non-clinical settings and clinical settings, clinicians review remotely. | Similar<br><br>For the proposed device, recordings are captured in non-clinical setting. |
| **Device main components** | <u>Hardware:</u><br>• A stethoscope Chest Piece:<br>o Stethoscope Adaptor<br>o TytoCare Device<br><br><u>Software:</u><br>• TytoCare Device Application<br>[runs on TytoCare Device]<br>• TytoCare User Application<br>[runs on the mobile device]<br>• TytoCare Clinician Dashboard<br>[runs on the clinician platform] | <u>Hardware</u>:<br>• A stethoscope Chest Piece:<br>o Stethoscope Adaptor<br>o TytoCare Device<br><br><u>Software:</u><br>• TytoCare Device Application<br>[runs on TytoCare Device]<br>• TytoCare User Application<br>[runs on the mobile device]<br>• TytoCare Clinician Dashboard<br>[runs on the clinician platform] | Same<br><br>Some of the software components of the proposed device include other function that are not subject to FDA's premarket review.<br><br>The TytoCare User Application is a non-medical device software.<br><br>The Clinician Application and the TytoCare Server software include |

| | Proposed Device | Predicate Device | Summary |
|---|---|---|---|
| | • TytoCare Server software [runs on the Tyto Server] | • TytoCare Server software [runs on the Tyto Server] | software functions subject to FDA premarket review and other functions that are not subject to FDA's premarket review. |
| **Device technology and operating principle** | User place the Tyto Stethoscope's adaptor in full contact with the patient's body, data is recorded and transmitted from the chest piece (*i.e.,* the The TytoCare device mounted with adaptor) to the user end unit (*i.e.,* a mobile device such as smartphone), via Wi-Fi, and then over the internet to the clinician end unit (*i.e.,* a clinician platform such as PC or laptop. | User place the Tyto Stethoscope's adaptor in full contact with the patient's body, data is recorded and transmitted from the chest piece (*i.e.,* the The TytoCare device mounted with adaptor) to the user end unit (*i.e.,* a mobile device such as smartphone), via Wi-Fi, and then over the internet to the clinician end unit (*i.e.,* a clinician platform such as PC or laptop. | Same |
| **System user interface** | • TytoCare Device LCD screen<br>• Smartphone device display<br>• Clinician Dashboard (*e.g.,* Tablet, PC, Laptop) | • TytoCare Device LDC screen<br>• Smartphone device display<br>• Clinician Dashboard (*e.g.,* Tablet, PC, Laptop) | Same |
| **Dimensions** | TytoCare device - 2.65 x 2.65 x 1.16 inch (67.5x67.5x29.5mm)<br>LCD, touch screen, 2"<br><br>Tyto Stethoscope adaptor – 1.57 x 1.53 inch (40 x 39 mm)<br>Diaphragm Diameter – 30mm | TytoCare device – 3.11 x 2.87 x1.85 inch (79x73x47mm)<br>LCD, touch screen, 2.4"<br><br>Tyto Stethoscope adaptor – 1.57 x 1.53 inch (40 x 39 mm)<br>Diaphragm Diameter – 30mm | TytoCare Device - Different<br><br>TytoCare Adaptor - Same |
| **Sensor type and technology** | Embedded acoustic piezoelectric contact sensor captures analog auscultation sound data, amplifies it, filters, digitizes and stores it. | Embedded acoustic piezoelectric contact sensor captures analog auscultation sound data, amplifies it, filters, digitizes and stores it. | Same |
| **Communication** | TytoCare Device – mobile device: Wi-Fi | TytoCare Device – mobile device: Wi-Fi | Same |

| | Proposed Device | Predicate Device | Summary |
|---|---|---|---|
| | Mobile device - server - clinician platform: Internet / HTTPS, WEBRTC | Mobile device - server - clinician platform: Internet / HTTPS, WEBRTC | |
| **Operating power** | 5V from a rechargeable battery in the TytoCare Device | 5V from a rechargeable battery in the TytoCare Device | Same |
| **Measurement frequency range and filters** | 20 – 3500 Hz<br>• Heart filter (Bell) – 20-1000Hz<br>• Lungs filter (Diaphragm) 20-3000Hz<br>• Wide filter- 20–3500 Hz | 20 – 3500 Hz<br>• Heart filter (Bell) – 20-1000Hz<br>• Lungs filter (Diaphragm) 20-3000Hz<br>• Wide filter- 20–3500 Hz | Same |
| **Heart rate Algorithm** | AI enabled algorithm<br><br>Accuracy of ~5 BPM or ~10% variation, whichever is greater. | Accuracy of ~5 BPM or ~10% variation, whichever is greater. | Same Accuracy<br><br>The new algorithm's AI-enabled modality for analysis based on stethoscope recordings does not raise different questions of safety or effectiveness.<br><br>A reference device was included to support that an AI-enabled algorithm designed for the analysis of stethoscope recordings was previously cleared by the FDA (K220766). |

**Table 1:** Comparison table of the Tyto Care Tyto Stethoscope (G3) with the predicate device

The proposed Tyto Stethoscope (G3) has the same intended use as the predicate device (Tyto Stethoscope, K181612): both are electronic stethoscopes designed to capture and transmit heart and lung sounds for clinician review to support medical diagnosis. The only difference in use environment is that the proposed device is intended for lay users in non-clinical settings, while with the predicate recordings are acquired in a clinical setting as well; both remain OTC devices with clinician review of all recordings. The technological characteristics of the Tyto Stethoscope G3 are similar to the predicate, with minor hardware differences such as a new chipset (due to discontinuation), removal of an audio jack, and a slightly smaller but with the same resolution display. The stethoscope adaptor remains mechanically and electronically identical aside from enclosure materials. Software changes include updated firmware to support new hardware, user interface refinements, and the inclusion of AI-enabled algorithms for heart rate calculation and recording quality feedback (A reference device was included to support that an AI-enabled algorithm designed for the analysis of stethoscope recordings was previously cleared by the FDA (K220766). These modifications do not affect the core functionality, intended use, or user workflow and do not raise new questions of safety or effectiveness. The principles and mode of operation remain unchanged, and all supported exams, frequency ranges, and filtering logic are consistent with the predicate. Therefore, the Tyto Stethoscope (G3) is substantially equivalent to its predicate device.

**Performance evaluation:**

The Tyto Stethoscope (G3) was subject to performance evaluation following methodology similar to the ones used to test the predicate device. A testing plan was developed and performed to verify that the Tyto Stethoscope (G3) meets its specifications. The main aspects of the testing plan included:

- **SW verification and validation** - The software including both custom-developed software and OTS software, have been verified and validated and have been demonstrated to be safe and effective for its intended use. The software documentation level is basic per *Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff*, dated June 14, 2023.
- **Cybersecurity**- all the applicable information to reflect effective cybersecurity management and to address the FDA's recommendations described in Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems

Under Section 524B of the FD&C Act, issue date March 2023, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issue date September 2023.

- **Human factors validation** – the minor user interface modifications did not introduce new critical tasks and didn't impact existing critical tasks. Therefore, no additional human factors validation was required and the human factors testing for the predicate device was applicable.
- **Electrical Safety and Electromagnetic compatibility** -The Tyto Stethoscope (G3) has been tested by an external laboratory. Testing results demonstrate that the Tyto Stethoscope (G3) is compatible with the requirements of the IEC 60601-1 Edition 3.2 2020-08, 60601-1-11 Edition 2.1 2020-07, IEC 60601-1-2 Edition 4.1 2020-09 and IEC TR 60601-4-2 Edition 1.0 2016-05 standards.
- **Biocompatibility** - The biocompatibility of the Tyto Stethoscope was evaluated via a biological safety assessment process in accordance with ISO 10993-1:2018, ISO 14971:2019 and *FDA's guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, the Tyto Stethoscope (G3) is considered biocompatible for its intended use.
- **Manual cleaning and low-level disinfection validation** – validation was conducted in accordance with ISO 17664:2021, AAMI TIR12:2020 (R2023), and AAMI ST98:2022.
- **Bench testing**:

  **Heart Rate Algorithm Performance validation** - The Tyto Stethoscope uses Artificial intelligence enabled technology to calculate heart rate from the heart sounds recorded by the Tyto Stethoscope. The accuracy of the algorithm was evaluated on a retrospective dataset and laboratory dataset. The validation dataset included 200 recordings, 59 from a controlled laboratory dataset and 141 from a real-world dataset. The real-world dataset is composed of recordings obtained from real-world use of the predicate device, the FDA-cleared Tyto Stethoscope (K181612), which were transmitted to the proposed device.

  The ground truth of the HR values was determined by three independent clinicians and calculated as the average of all acceptable evaluations. Accuracy was defined as the algorithm's HR measurement matching the reference value within ±5 beats per

minute (BPM) or 10% (whichever is greater) across the 30–250 BPM range. The demographics of the real-world validation dataset are presented hereunder:

| | **Total** |
|---|---|
| **Age** | |
| **<18** | 58 (41.1%) |
| **≥18** | 83 (58.9%) |
| **Gender** | |
| **Male** | 71 (50.3%) |
| **Female** | 70 (49.7%) |
| **Abnormal sounds** | |
| **Recordings with abnormal heart sounds** | 20 (14.18%) |
| **Recordings without abnormal heart sounds** | 121 (85.82%) |

**Table #2**: Real world dataset validation dataset demographics

The algorithm achieved 100% accuracy (98.1–100% confidence interval) across all cases, exceeding the predefined primary endpoint threshold of 90%.

| **Measure** | **n / N** | **Estimate** | **95% LCI** | **95% UCI** | **Endpoint Assessment** |
|---|---|---|---|---|---|
| **Accuracy** | 200 / 200 | 1.0 | 0.9817 | 1.0 | 0.9817 > 0.9 - PASS |

**Table #3:** Accuracy Primary Endpoint Evaluation

**Comparative performance evaluation -**A comparative performance evaluation was conducted between the proposed device and the predicate device to verify equivalent technical performance and confirm no significant changes in stethoscope functionality. The assessment focused on key parameters including frequency response (FR), maximum input level, and noise level. The proposed device met all protocol-defined acceptance criteria and demonstrated performance equivalent to the predicate device.

**Heart and lung recordings quality assessment -** A retrospective validation study evaluated the accuracy of the heart and lung recording quality assessment algorithms in determining whether sound recordings captured with the Tyto Stethoscope are of sufficient quality for clinical assessment. The study concluded that the Tyto Stethoscope reliably identifies whether heart and lung recordings are sufficient or insufficient for clinical assessment.

**Conclusion**

The Tyto Stethoscope (G3) and its predicate device have the same intended use and similar technological characteristics. The minor technological differences between the Tyto Stethoscope (G3) and its predicate device do not raise different questions of safety or effectiveness. Test results indicated that the Tyto Stethoscope (G3) functions as expected and is as safe and effective as its predicate devices for its intended use. It is, therefore, concluded that the Tyto Stethoscope (G3) is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.