June 2, 2026

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

Re: K252844
Trade/Device Name: Tyto Insights for Wheeze Detection (with PCCP)
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic Pulmonary-Function Interpretation Calculator
Regulatory Class: Class II
Product Code: PHZ
Dated: April 29, 2026
Received: April 29, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.06.02 10:44:23 -04'00'

For

Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252844

Device Name
Tyto Insights for Wheeze Detection (with PCCP)

Indications for Use *(Describe)*
The Tyto Insights for Wheeze Detection (with PCCP) is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submission Number	K252844
Submitter Name and Address:	Tyto Care Ltd. 14 Beni Gaon Street Netanya, Israel, 4250803
Contact Person:	Stella Raizelman Perry RA & QA Director Email: stellar@tytocare.com Phone Number: +972 72-2210750 Fax Number: +972 72-2210752
Establishment Registration Number:	3012678246
Date Prepared:	April 28, 2026
Device Trade Name(s):	Tyto Insights for Wheeze Detection (with PCCP)
Device Common Name:	Tyto Insights for Wheeze Detection (with PCCP)
Classification:	**Name:** Diagnostic pulmonary-function interpretation calculator **Product code:** PHZ **Regulation No:** 21 CFR 868.1900 **Class**: II **Panel:** Anesthesiology

Predicate Device(s):

Device name	510(k) No.	Date of Clearance
Tyto Insights for Wheeze Detection	K232237	December 13, 2023

Reference Device(s):

Device name	510(k) No.	Date of Clearance
Tyto Insights for Rhonchi Detection	K243567	April 07, 2025

The reference device is cited to demonstrate consistency of Predetermined Change Control Plan (PCCP) elements with the subject device.

Intended use / indication for use statement

TheTyto Insights for Wheeze Detection (with PCCP) is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.

Device description

The Tyto Insights for Wheeze Detection is a web-based (AI) enabled software system designed to aid in the clinical assessment of lungs auscultation sound data by analyzing recorded lung sounds to determine whether a Wheeze is detected within the recorded sound data.

The Tyto Insights for Wheeze Detection Software is intended to process recordings from the FDA-cleared compatible Tyto Stethoscope (Tyto Stethoscope, K181612). The acquisition of the acoustic data (recordings) is carried out by a professional user in a clinical environment or by a lay- user in a non-medical environment, in compliance with the labeling of the Tyto Stethoscope. The system is composed of the following sub-systems:

1. The Tyto Insights for Wheeze Detection Application Server (APS) communicates with the Tyto Insights for Wheeze Detection Algorithm Server (ALS) and implements an application programming interface (API) for communication with the telehealth server.
2. The Tyto Insights for Wheeze Detection Algorithm Server (ALS) receives an audio file as input and returns an analysis result of positive or negative regarding whether a wheeze was detected as output.
3. The Tyto Insights for Wheeze Detection Web Server (WBS) provides a graphic indication whether a wheeze is detected in the recording. It can be utilized both in patient and clinician side.

All the software subsystems (servers and storage) are hosted in the cloud and communicate through IP network.

The recordings from the compatible Tyto Stethoscope (K181612) are sent by the third-party point of care app to the clinician app through the telehealth server. The telehealth server sends the set of lung sound recordings to the Tyto Insights for Wheeze Detection web server using its dedicated API. The AI enabled algorithm runs automatically and returns a response for each audio file with the indication of wheeze to the telehealth server which sends a response to both the clinician side and the patient side.

Substantial Equivalence to Predicate Devices

The following table compares Tyto Insights for Wheeze Detection (with PCCP) to the predicate and reference devices.

Table 1. Substantial Equivalence Summary

	Device	**Predicate Device**	**Reference Device**	**Summary**
Device Name	Tyto Insights for Wheeze Detection (with PCCP)	Tyto Insights for Wheeze Detection	Tyto Insights for Rhonchi Detection	NA
Device Manufacturer	Tyto Care Ltd.	Tyto Care Ltd.	Tyto Care Ltd.	Same
510(k) Number	K252844	K232237	K243567	NA
Device Class	Class II	Class II	Class II	Same
Review Panel	Anesthesiology	Anesthesiology	Anesthesiology	Same
Product code	PHZ	PHZ	PHZ	Same
Regulation number	21 CFR 868.1900	21 CFR 868.1900	21 CFR 868.1900	Same
Device Classification Name	Abnormal breath sound device	Abnormal breath sound device	Abnormal breath sound device	Same

	Device	Predicate Device	Reference Device	Summary
Intended use and indication for use	The "Tyto Insights for Wheeze Detection" is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.	The "Tyto Insights for Wheeze Detection" is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.	The Tyto Insights for Rhonchi Detection is a prescription-use artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA 510k cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Rhonchi" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Rhonchi Detection result. Healthcare providers should consider the device result in conjunction with recording	Same as the predicate device.

	Device	Predicate Device	Reference Device	Summary
			and other relevant patient data.	
Type of use	Over-The-Counter Use	Over-The-Counter Use	Prescription use	Same as the predicate device
Intended users	Professional users and lay users (18-65 years old).	Professional users and lay users (18-65 years old).	Professional users and lay users (18-65 years old).	Same
Intended patient population	Patients of 2 years and older	Patients of 2 years and older	Patients of 2 years and older	Same
Intended environment	Non-clinical (home) and clinical	Non-clinical (home) and clinical	Non-clinical (home) and clinical	Same
Input	Lung sounds recorded by compatible Tyto Stethoscope (K181612)	Lung sounds recorded by compatible Tyto Stethoscope (K181612)	Lung sounds recorded by compatible Tyto Stethoscope (K181612)	Same
Signal length	Recordings are processed in segments of up to 12 seconds while signals shorter than 6 seconds will not be processed.	Recordings are processed in segments of up to 12 seconds while signals shorter than 6 seconds will not be Processed.	Recordings are processed in segments of up to 12 seconds while signals shorter than 6 seconds will not be Processed.	Same
Algorithm	Machine learning based (Neural network)	Machine learning based (Neural network)	Machine learning based (Neural network)	Same as the predicate device.
Output	• Positive (wheeze suspected), • Negative (Wheeze not suspected), • The Tyto Insights for Wheeze Detection was	• Positive (wheeze suspected), • Negative (Wheeze not suspected), • The Tyto Insights for Wheeze Detection was	• Positive (Rhonchi suspected), • Negative (Rhonchi not suspected), • The Tyto Insights for Rhonchi Detection was	Same as the predicate device.

	Device	Predicate Device	Reference Device	Summary
	not able to analyze the recording	not able to analyze the recording	not able to analyze the recording	
Performance	AUC :0.96 (0.95– 0.98) Estimate two-sided 95% Cl): Sensitivity: 0.55 [0.43 – 0.65] Specificity: 0.99 [0.99 – 1.00]	AUC :0.96 (0.95– 0.98) Estimate two-sided 95% Cl): Sensitivity: 0.55 [0.43 – 0.65] Specificity: 0.99 [0.99 – 1.00]	AUC: 0.96 (0.92–0.98) Estimate two-sided 95% Cl): Sensitivity: 0.60 (0.50-0.69) Specificity: 0.99 (0.97 - 1.00)	Same as the predicate.
User interface	Web view	Web view	Web view	Same
Predetermined Change Control plan (PCCP)	Includes PCCP (submitted for FDA review in this 510(k))	Not included	Includes FDA authorized PCCP	The predicate device didn't include PCCP. The types of modifications, data management practices, re-training practices, performance evaluation methods, and update procedures for the subject device are consistent with those of the reference device.

The intended use of the subject device is identical to that of the predicate device. The purpose of this 510(k) submission is to obtain FDA's review and authorization of a Predetermined Change Control Plan (PCCP) for the subject device. The only additional difference from the predicate device is a minor software update in which third-party libraries were updated to address known vulnerabilities, consistent with Tyto Care's software development lifecycle and cybersecurity procedures. The subject device maintains the same technological characteristics as the predicate device. This minor software update does not alter these characteristics and does not raise new questions of safety or effectiveness.

Standards Conformance:

- ANSI AAMI ISO 14971:2019, Medical devices - Application of risk management to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes
- ISO 15223-1 Fourth edition 2021-07, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical device.

Performance evaluation:

- 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. All required items related to software as required by FDA guidance for Basic Documentation Level have been included in this submission.
- 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 February 2026 and in the other FDA's applicable policies have been included in this submission.

- Performance evaluation - The minor software update did not impact device performance. The clinical validation previously conducted for the predicate device remains applicable to the subject device. Accordingly, no additional performance validation was required.
- Human factors validation - The minor software update did not introduce any modifications to the user interface, did not create new critical tasks, and did not affect existing critical tasks. Therefore, no additional human factors validation was necessary. The evaluations conducted for the predicate device remain fully applicable to the subject device.

Predetermined Change Control Plan (PCCP)

Predetermined Change Control Plan (PCCP) that specifies anticipated modifications to the Tyto Insights for Wheeze detection device is included in this submission. The same type of software modifications, data management practices, re-training practices, performance evaluation methods, and update procedures to establish substantial equivalence as were applied for the *Tyto Insights for Rhonchi Detection* (K243567), the reference device, were followed.

The table below includes a description of the software modifications that can be made to the algorithms in the device subject to the authorized PCCP as well as a description of the test methods that will be used to support substantial equivalence determination.

Detailed list of changes	**Test Methods**	**Acceptance criteria to establish substantial equivalence**
1. <u>Modifications related to performance specifications enhancement:</u> Re-training of the ML model with additional data to improve the device clinical performance, as measured by sensitivity and specificity, compared to the most recently validated and released version of the device, while maintaining the same type and range of input signal.	• Software verification and validation • Clinical performance Validation. Retrospective study on dataset of the compatible Tyto Stethoscope recordings that are representative of the intended recorded patient population (data will be acquired by the real-world use of the Tyto Stethoscope) .	• Software verification and validation meet the requirements • Clinical performance Validation: **<u>Stand alone:</u>** Accuracy of device – Sensitivity, Specificity, PPV, NPV **<u>Co-Primary endpoints:</u>** • Sensitivity of the modified device calculated on the new validation dataset. Specificity of the modified device calculated on the new validation dataset.

		Success criteria: The modification will be considered successful only if the lower bound of the 95% confidence interval for both sensitivity and specificity is not lower than the corresponding lower confidence bounds of the most recently validated and released version of the device **Secondary Endpoint** • The PPV and NPV of the newly trained algorithm compared to the PPV and the NPV of the most recently validated and released version of the device • Performance of the modified device (including sensitivity and specificity) will also be descriptively evaluated across the following clinically relevant subgroups: age group (2–18 years vs. >18 years), gender, and user type (lay user vs. healthcare professional) and stethoscope model (e.g., due to prior modifications).
2. Modifications related to technical performance specifications. Modification of data preprocessing methodologies /data augmentation methodologies and hyper-parameters tuning to improve the technical performance characteristics (including running time, memory consumption and CPU utilization). These changes are implemented without modifications to the core model architecture, intended use, or output of the device.	• Software verification and validation • Verification testing will be conducted for the improved computational parameters • Clinical performance Validation. Retrospective study on dataset of the compatible Tyto Stethoscope recordings that are representative of the intended recorded patient population (data will be acquired by the real-world use of the Tyto Stethoscope).	• Software verification and validation meet the requirements • Verification testing meets the requirements • Clinical performance Validation: **Stand-alone:** Accuracy of device – Sensitivity, Specificity, PPV, NPV **Co-Primary endpoints:** • Sensitivity of the modified device calculated on the new validation dataset. Specificity of the modified device calculated on the new validation dataset. **Success criteria:** The modification will be considered successful only if the lower bound of the 95% confidence interval for both sensitivity and specificity is not lower than the

		corresponding lower confidence bounds of the most recently validated and released version of the device. Meeting both endpoints is required for the modification to be declared successfully. **Secondary Endpoint** • The PPV and NPV of the modified algorithm will be compared to the PPV and the NPV of the most recently validated and released version of the device. • Performance of the modified device will be descriptively evaluated across the following clinically relevant subgroups: age group (2–18 years vs. >18 years), gender, and user type (lay user vs. healthcare professional) and stethoscope model (e.g., due to prior modifications).
3. Modifications related to device input expansion Expanding the algorithm to include new sources of the same signal type (different model of FDA compatible Stethoscope with equivalent audio acquisition specifications). Modification is limited to expanding to electronic stethoscopes that have FDA 510k clearance (for over-the-counter use) at the time that the proposed modification is made.	• Software verification and validation • Clinical performance Validation. Retrospective study on dataset of the compatible Stethoscope recordings that are representative of the intended recorded patient population (data will be acquired by the real-world use of the applicable Stethoscope models).	• Software verification and validation meet the requirements • Clinical performance Validation: **Stand-alone:** Accuracy of device – Sensitivity, Specificity, PPV, NPV Co-Primary endpoints: • Sensitivity of the modified device calculated on the new validation dataset. • Specificity of the modified device calculated on the new validation dataset. **Success Criteria:** The modification will be considered successful only if the lower bound of the 95% confidence interval for both sensitivity and specificity is not lower than the corresponding lower confidence bounds of the most recently validated and released version of the device. Meeting both endpoints is required for the modification to

		be declared successfully. **<u>Secondary Endpoint</u>** • The PPV and NPV of the newly trained algorithm compared to the most recently validated and released version of the device calculated on new validation dataset. • Performance of the modified device (including sensitivity and specificity)will also be descriptively evaluated across the following clinically relevant subgroups: age group (2–18 years vs. >18 years), gender, user type (lay user vs. healthcare professional), and input device. Subgroup analysis by input device will include performance evaluation for each compatible stethoscope model.

Conclusion

Tyto Insights for Wheeze Detection (with PCCP) has the same intended use, indication for use and technological characteristics as the predicate device.

The proposed modifications under the PCCP and the minor software differences do not raise new questions of safety and effectiveness. Thus, we conclude that the Tyto Insights for Wheeze Detection (with PCCP) is substantially equivalent, i.e., as safe and effective as the predicate device.