February 24, 2023

Tyto Care Ltd.
Stella Perry
RA&QA Director
14 Beni Gaon Street
Netanya, 4250803
Israel

Re: K221614
Trade/Device Name: TytoCare Lung Sounds Analyzer
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic Pulmonary-Function Interpretation Calculator
Regulatory Class: Class II
Product Code: PHZ
Dated: January 26, 2023
Received: January 26, 2023

Dear Stella 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
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Anesthesia Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221614

Device Name
TytoCare Lung Sounds Analyzer

Indications for Use *(Describe)*
The TytoCare Lung Sounds Analyzer is an over-the-counter decision support software system used in the evaluation of lung sounds in adults and children (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 TytoCare Lung Sounds Analyzer result. Healthcare provider 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

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:	February 24, 2023
Device Trade Name(s):	TytoCare Lung Sounds Analyzer
Device Common Name:	TytoCare Lung Sounds Analyzer
Classification:	**Name:** Diagnostic pulmonary-function interpretation calculator **Product code:** PHZ **Secondary product code**: DQD **Regulation No:** 21 CFR 868.1900 **Class:** II **Panel:** Anesthesiology

Predicate Device(s):

Device name	**510(k) No.**	**Date of Clearance**
wheezo WheezeRate Detector (by Respiri Limited)	K202062	March 11, 2021

Reference Device(s):

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

Intended use / indication for use statement

The TytoCare Lung Sounds Analyzer is an over-the-counter decision support software system used in the evaluation of lung sounds in adults and children (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 TytoCare Lung Sounds Analyzer result. Healthcare provider should consider the device result in conjunction with recording and other relevant patient data.

Device description

The TytoCare Lung Sounds Analyzer is a web-based 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 TytoCare Lung Sounds Analyzer 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 TytoCare Lung Sounds Analyzer Application Server (APS) communicates with the TytoCare Lung Sounds Analyzer Algorithm Server (ALS) and implements an application programming interface (API) for communication with the telehealth server.
2. The TytoCare Lung Sounds Analyzer 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 TytoCare Lung Sounds Analyzer 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.

Substantial Equivalence to Predicate Devices

The following table compares the TytoCare Lung Sounds Analyzer to the predicate and reference device devices:

	Device	Predicate	Reference device	Summary
Device Name	TytoCare Lungs Sounds Analyzer	wheezo WheezeRate Detector	Tyto Stethoscope (OTC)	NA
Device Manufacturer	Tyto Care Ltd.	Respiri Limited	Tyto Care Ltd.	NA
510(k) Number	K221614	K202062	K181612	NA
Device Class	Class II	Class II	Class II	Same
Review Panel	Anesthesiology	Anesthesiology	Cardiovascular	Same
Product code	PHZ DQD	PHZ	DQD	Same
Regulation number	21 CFR 868.1900	21 CFR 868.1900	21 CFR 870.1875	Same
Classification Name	Diagnostic pulmonary-function interpretation calculator	Diagnostic pulmonary-function interpretation calculator	Stethoscope	Same
Intended use and indication for use	The TytoCare Lung Sounds Analyzer is an over-the-counter decision support software system used in the evaluation of lung sounds in adults and children (2 years and older). It automatically analyzes the acoustic signal	Wheezo is intended to detect and record abnormal breath sounds (continuous adventitious breath sounds/CABS) at the windpipe (trachea), reported as WheezeRate in adults and children (2	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	Same Both the predicate device and the subject device have the same intended use and indication for use in that both are intended to detect specific and abnormal breath sounds in the same

	Device	Predicate	Reference device	Summary
	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 TytoCare Lung Sounds Analyzer result. Healthcare provider should consider the device result in conjunction with recording and other relevant patient data.	years and older). A licensed health care professional's advice is required to understand the meaning and importance of the wheezo readings.	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 professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.	intended patient population (adult and pediatric) by the same user [Health Care Professional (HCP)] when self-administered by patient and/or the HCPs. Both devices are only intended to be interpreted by HCP and HCP advice is required for the patient to understand their result. Both are labeled OTC.
Type of use	Over-The-Counter Use	Over-The-Counter Use	Over-The-Counter Use	Same
Intended users	Intended to be used by professional users and lay users.	Intended to be used by lay users	Intended to be used by professional users and lay users	Similar, the TytoCare Lung Sounds Analyzer is intended for clinicians and lay users.

	Device	Predicate	Reference device	Summary
Intended patient population	Intended for patients of 2 years and older	Intended for patients of 2 years and older	Intended for patients of all ages	Same
Intended environment	Non-clinical (home) and clinical	Non-clinical (home)	Non-clinical (home) and clinical	Similar. the TytoCare Lung Sounds Analyzer is intended for both home and clinical environment
Form	Stand-alone software system	Hardware and Software, hand-held stand-alone device used with smartphone	Hardware and Software, hand-held stand-alone device used with smartphone	Different. The acquisition of lung sounds of both devices is conducted by FDA cleared device, therefore there is no new question of effectiveness.

	Device	Predicate	Reference device	Summary
Device composition	The following modules compose the TytoCare Lung Sounds Analyzer: • The TytoCare Lung Sounds Analyzer Application Server (APS) • The TytoCare Lung Sounds Analyzer Algorithm Server (ALS) • The TytoCare Lung Sounds Analyzer 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.	The wheezo WheezeRate Detector consists of: • Wheezo Sensing Device • Wheezo App • Cloud server	Hardware: • A stethoscope Chest Piece: o Stethoscope Adaptor o TytoCare Device Software: • TytoCare Device Application [runs on TytoCare Device] • TytoCare Application [runs on the mobile device] • Clinician Application [runs on the clinician platform] • Server software [runs on the Tyto Server]	Different The TytoCare Lung Sounds Analyzer is a Stand-alone software system used with compatible Tyto Stethoscope to record lung sounds. The Wheezo is Hardware and Software, hand-held device used with smartphone. Both devices acquire lung sounds and provide indication on the presence of wheeze to the user. The difference doesn't raise new questions of safety or effectiveness.
Input	Lung sounds recorded by compatible Tyto Stethoscope	Lung sounds recorded by the wheezo device	Lung sounds recorded by the Tyto Stethoscope	Different Both devices acquire lung sounds with device cleared by the FDA for that purpose

	Device	Predicate	Reference device	Summary
				The difference doesn't raise new questions of safety or effectiveness
Device technology and operating principle	The recordings are created by the compatible Tyto Stethoscope (K181612) and 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 the lung sound recordings to the TytoCare Lung Sounds Analyzer web server using its dedicated API. The telehealth server subsequently sends the link to results and the relevant UI web view to the point of care app and clinician app. The algorithm runs automatically and returns a response for each audio file with the indication of wheezes to the telehealth server, which sends a response to both the	User places sensor on their neck for 30 seconds to perform a passive manoeuvre. The device records, analyses the lung sounds and quantifies the presence of wheezing. The wheezo transfers a user's breath sound data to the App using a Smart Device. The sound data is analyzed in the algorithm, which is integrated inside the App and runs on the Smart Device.	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. Both devices acquire lung sounds with device cleared by the FDA for that purpose, analyze the lung sounds and provide indication on the presence of wheeze.

	Device	Predicate	Reference device	Summary
	clinician side and the patient side.			
Sensor type and technology	NA, software only	Microphone sensor (made of silicon) acquires, filters and digitizes the breath sounds.	Embedded acoustic piezoelectric contact sensor captures analog auscultation sound data, amplifies it, filters, digitizes and store it.	Different but the difference doesn't raise new questions of safety or effectiveness. The subject device is intended to be used with compatible Tyto Stethoscope (reference device) to record lung sounds. The predicate and the reference devices both use a handheld piece with embedded sensor in the chest piece to acquire lung sounds. The safety and performance of the reference device sensor's type and technology has been established previously for acquiring lung sounds by means of FDA clearance.
Sensor location	NA, software only	Trachea	Top part of the chest and the top part of patient's back (Left Upper Lobe, Left Lower Lobe, Right Upper Lobe, Right Lower Lobe).	Different but the difference doesn't raise new questions of safety or effectiveness. The subject device is intended to be used with compatible Tyto Stethoscope (reference device) to record lung sounds. The safety and performance of the reference device sensor's location for acquiring lung sounds has been established before by means of FDA clearance.

Signal length	The length of the signal is dictated by the recording process of the compatible Stethoscope. The subject device processes the recordings in segments of up to 12 seconds while signals shorter than 6 seconds will not be processed.	30 seconds	Variable	Different but the difference doesn't raise new questions of safety or effectiveness. The safety and performance of the different signal length that is used in the process of lung sound acquisition by numerous FDA cleared electronic stethoscopes including the reference device as well as Diagnostic Pulmonary-Function Interpretation Calculators including the predicate device was established. Thus, the impact of different signal length on performance does not raise a new question of safety or performance.
Data transfer and storage	The telehealth server sends the list of the recordings (identified by a unique identifier and time stamp) to the TytoCare Lung Sound Analyzer web server using its dedicated API. The server executes the TytoCare Lung Sounds Analyzer which runs the algorithm and provides the results. Then the TytoCare Lung Sound Analyzer web	Every recording is automatically uploaded to the cloud. However, if an Internet connection is not available, up to 20 most recent recordings will be stored locally on the smartphone.	The stethoscope recordings are transferred to the server using the software of the Tyto Stethoscope. However, if an Internet connection is not available, most recent recordings will be stored locally on the Tyto Stethoscope.	Different medical device data system but the difference doesn't raise new questions of safety or effectiveness.

	Device	Predicate	Reference device	Summary
	server initiates the web user interface. All the software subsystems (server and storage) are hosted in the cloud and communicate through IP network.			
Output	• Positive (wheeze suspected), • Negative (Wheeze not suspected), • The TytoCare lungs sounds analyzer was not able to analyze the recording	Detection and quantification of wheeze presence, expressed as "wheeze rate".	NA	Different but no new questions of safety and effectiveness as both the device and the predicate use software algorithm to detect abnormal breath sound (wheeze) in lung recordings.
Accuracy	Non-inferior to clinical readers	Non-inferior to clinical readers	NA	Same
User interface for point of care and clinician apps	Web view	Mobile App	• TytoCare Device LCD screen • TytoCare mobile App	Same Both predicate and reference device use a proprietary mobile App for recordings acquisition and management. Different UI of the device using web-view doesn't raise new questions of safety or effectiveness.

Table 1. **Substantial Equivalence Summary**

The TytoCare Lung Sounds Analyzer and the predicate device have the same intended use and indication for use in that both are intended to detect specific and abnormal breath sounds in the same intended patient population (adult and children's) by the same user [Health Care Professional (HCP)] when administered by patient and/or the HCPs. Both devices are only intended to be interpreted by HCP and HCP advice is required for the patient to understand their result. Both are labeled OTC.

The TytoCare Lung Sounds Analyzer is a stand-alone software system that has the same intended use as the predicate (automatically detect wheezes) but at the absence of the sensor technology that is built into the predicate device. The Tyto Stethoscope (K181612) that is source of the lung recordings for the TytoCare Lung Sounds Analyzer was added as reference device to this premarket notification to account for these technological differences. The compatible Tyto Stethoscope is FDA cleared thus the technical differences as far as the different input to the device and its predicate do not raise new or different questions of safety and effectiveness.

Both devices are intended to detect wheezes and the output conveys this information to the user. The question concerning the ability of a software (in both cases the recording is analyzed by proprietary software) to accurately detect abnormal breath sound is not new. The predicate utilizes software for the analysis thus it raised similar questions before. The different software algorithm does require that its accuracy will be substantiated with valid performance data (accuracy testing).
Both devices display the result to the user. The user interface is different but the difference does not raise new questions of safety and effectiveness as the predicate already introduced the questions concerning the impact of displaying the results to the same lay user. The different user interface does require that the substantial equivalence be based on performance evaluation (human factor testing).

Performance evaluation:

The TytoCare Lung Sounds Analyzer 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 TytoCare Lung Sounds Analyzer 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. The software is a Moderate Level of Concern (LOC) per FDA guidance.
- Cybersecurity- The cybersecurity assessment including cybersecurity risk analysis was performed per FDA guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.
- Human factors validation testing was conducted, human factors data supports that individuals are able to successfully self-select themselves for the device and the risk of self-diagnosis is effectively mitigated similar to the predicate device.
- Performance evaluation – the Technical (Analytical) accuracy has been characterized and the Clinical preference has been validated including reproducibility:

The performance of the TytoCare Lung Sounds Analyzer device in detecting wheeze in recordings acquired by the compatible Tyto Stethoscope has been evaluated on a retrospective validation dataset of Tyto Stethoscope recordings sourced from real world use of the Tyto Care FDA cleared Tyto Stethoscope. 371 recordings (86 recordings

were Wheeze positive and 285 negative, from a total of 359 patients) corresponded to the intended patient population of the TytoCare Lung Sounds Analyzer Software (Age >2 years). The validation data-set included recordings with known pre-existing conditions (COPD or Asthma) (7.28%). The demographics of the validation dataset are presented hereunder:

Table 2: Validation data-set demographics

			N=359 patients
Age Group (Years)			
	Wheeze Positive	Wheeze Negative	Total
2-18	63 (24.3%)	196 (75.7%)	259 (72.1%)
>=18	17 (17%)	83 (83%)	100 (27.9%)
Gender			
	Positive	Negative	Total
Male	49 (25.9%)	140 (74.1%)	189 (52.6%)
Female	31(18.2%)	139 (81.8%)	170 (47.3%)

To establish the ground truth, all of the recordings were read by three blinded experienced Pulmonologists at random, the binary ground truth was determined by majority vote of these three Pulmonologists.

For the characterization of the stand-alone accuracy, the automated binary result of the software has been compared to ground truth and specificity and sensitivity were calculated. This stand-alone accuracy is presented hereunder in table 3:

Table 3: The stand-alone accuracy of the TytoCare Lung Sounds Analyzer

Parameter	Estimate (two-sided 95% CI)
Sensitivity (Se)	0.69 (0.57–0.78)
Specificity (Sp)	0.92 (0.88–0.95)

For the characterization of the clinical performance the Area under the Receiver Operating Curve (AUC) for Wheeze detection by the device was compared to the clinical readers (Physicians non-Pulmonologists). To calculate the AUC the probability score was extracted from the device and compared to a 5-point likelihood score that was recorded by the clinical readers independently for every recording.

The primary endpoint was to establish that the clinical accuracy of the TytoCare Lung Sounds Analyzer software's is non- inferior to the clinical readers provided with a 5% non-inferiority margin. The secondary endpoint was the reproducibility of the software as compared to the readers.

Table 4: The clinical accuracy of the TytoCare Lung Sounds Analyzer as compared to Clinical readers.

Parameter	Estimate 95% two sides CI
AUC TytoCare Lung Sound Analyzer	0.91 (0.86–0.94)
AUC Clinical readers	0.83 (0.78–0.86)

The AUC of the device was 0.91 (0.86–0.94) compared to the reader's AUC of 0.83 (0.78–0.86). The difference in AUC was 0.09 (0.04–0.13) which supports the non–inferiority (0.04 > margin of –0.05) of the device compared to the reader. Non-inferiority was established also when confounders such as age groups (<2, 2-6, >6 yo) and the relevant pre-existing conditions (Asthma or COPD) were accounted for in subgroup analysis.

Table 5: Reproducibility of device compared to the clinical readers in the detection of wheezes.

Parameter	Kappa	LCI	UCI
Clinical Readers	0.6134	0.5183	0.7016
TytoCare Lung sounds analyzer	1.0000	1.0000	1.0000
TytoCare Lung sounds analyzer – Clinical Readers	0.3866	0.2984	0.4817

LCI – lower bound of two–sided 95% confidence interval; UCI – upper bound of two–sided 95% confidence interval

Standards applied

- 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
- IEC 62366-1 Edition 1.1 2020-06, Medical devices - Part 1: Application of usability engineering to medical devices

Conclusion

The TytoCare Lung Sounds Analyzer Software has the same intended use and similar indication for use as the predicate. The TytoCare Lung Sounds Analyzer is only compatible with the reference FDA cleared TytoCare Stethoscope that provides the input stethoscope recording. Therefore, the technological differences in sensor technology, anatomical recording site, signal length and user interface as compared to the predicate do not raise new/different questions of safety and effectiveness relative to the reference device. The differences in the user interface and software algorithm do not raise new/different questions of safety and effectiveness. These differences were evaluated for their effect on safety and performance using a performance evaluation for device accuracy that followed the same method used to substantiate the predicate device and the results demonstrated that similarly the TytoCare Lung Sounds Analyzer is as safe and as effective as the predicate in that its accuracy in detecting wheeze is non inferior to that of the physician. Human factors data supports that the TytoCare Lung Sounds Analyzer has been found to be as safe and as effective for the intended users, uses and use environments. Thus, we conclude that the TytoCare Lung Sounds Analyzer is substantially equivalent. i.e. as safe and as effective as the predicate device.