Tyto Care Ltd.
% Dave Yungvirt
Official Third Party Correspondent
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

December 17, 2018

Re: K181612
Trade/Device Name: Tyto Stethoscope (OTC)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: December 4, 2018
Received: December 6, 2018

Dear Dave Yungvirt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S5

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181612

Device Name
Tyto Stethoscope (OTC)

Indications for Use *(Describe)*
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 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.

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

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Tyto Care Ltd. 12 Haomanut Street Netanya, Israel, 4250445
Contact Person:	Stella Raizelman Perry RA Director Email: stellar@tytocare.com Phone Number: +972 72-2210750 Fax Number: +972 72-2210752
Establishment Registration Number:	3012678246
Date Prepared:	November 28, 2018
Device Trade Name(s):	Tyto Stethoscope (OTC)
Device Common Name:	Electronic Stethoscope
Classification:	**Name:** Electronic Stethoscope **Product code:** DQD **Regulation No:** 21 CFR 870.1875 **Class:** II **Panel:** Cardiovascular
Predicate Device(s):	
Primary:	

Device name	**510(k) No.**	**Date of Clearance**
Tyto Stethoscope	K160401	October 19, 2016

The OTC use of an electronic stethoscope is supported by a second predicate, the CliniCloud Stethoscope (K173448) which is similarly cleared for over the counter use in periodic recording of lung and heart sounds.

Secondary:

Device name	510(k) No.	Date of Clearance
CliniCloud Stethoscope	K173448	January 25, 2018

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 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 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.

Device description

The Tyto Stethoscope (OTC) is designed for use by professional as well as lay users in clinical or non-clinical environments. It enables four types of stethoscope exams: Heart, Lungs, Heart Rate and Audio (Audio is for clinician only). The operation process of the Tyto Stethoscope uses four (4) primary functional elements:

(1) The Tyto Stethoscope (composed of a Stethoscope Tip and a Base Unit – Tyto Device and supported with proprietary software).

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

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

(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 Clinician App is running).

Two operational flows are optional for using the Tyto Stethoscope: 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, recording the data and sending to a clinician, review of the recorded measurements by the clinician, and user receiving a written summary from the clinician presenting his/her assessment and/or recommendations. While in the store-and-forward flow the user can perform 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.

Substantial Equivalence to Predicate Devices:

The Tyto Stethoscope (OTC) has the same intended use, and substantially similar indications for use, and fundamental technological characteristics as its primary and secondary predicate devices, the Tyto Stethoscope and the CliniCloud Stethoscope.

The Tyto Stethoscope (OTC) is the same device as the primary predicate Tyto Stethoscope (K160401) with a modification to the indications for use for OTC use of the device. This OTC indication is consistent with the secondary predicate, the CliniCloud Stethoscope.

Any minor differences in indications or technology between the Tyto Stethoscope (OTC) and its predicates do not raise different questions of safety or effectiveness. Furthermore, testing demonstrates that the performance of the Tyto Stethoscope (OTC) is comparable to its predicate devices as the device is technologically the same as the primary predicate Tyto Stethoscope. Consequently, it is concluded that the Tyto Stethoscope can be considered substantially equivalent to its primary and secondary predicate devices.

Performance Testing:

The Tyto Stethoscope (OTC) has the same technological characteristics as the primary predicate Tyto Stethoscope device (K160401), and accordingly, the

performance data collected to evaluate the safety and efficacy of the cleared version of the device is still applicable.

A testing plan was developed and performed in order to verify that the Tyto Stethoscope (K160401) meets its specifications and demonstrates, based on comparable characteristics, similar performance and safety as compared to its predicate devices (K102893 and K083903). The main aspects of the testing plan are presented below:

- Electrical safety and electromagnetic compatibility testing (according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-2)
- Biocompatibility assessment
- Performance testing (e.g., stethoscope performance, pseudo clinical, heart rate measurement, wireless coexistence)
- SW validation testing and
- A usability study

Conclusion

Based on the technological characteristics of the devices and the intended use, Tyto Care believes that the ***Tyto Stethoscope (OTC)*** and its predicate devices are substantially equivalent. The differences do not raise any new issues of safety or effectiveness.