DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 19, 2016

Tyto Care Ltd.
Dr. Orna Oz
President
155 Bialik St.
Ramat Gan, 5252346 IL

Re: K160401
Trade/Device Name: Tyto Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: September 13, 2016
Received: September 13, 2016

Dear Dr. Orna Oz,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K160401

Device Name

Tyto Stethoscope

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 for use by professional users in a clinical environment or in conjunction with patients or lay users in a non-clinical environment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
510(K) Number K160401

Applicant's Name:

Tyto Care Ltd.
12 Haomanut Street
Netanya, 4250445, Israel
Tel: +972-72-2210750
Fax: +972-72-2210752

Contact Person:

Ophir Lotan
Tyto Care Ltd.
12 Haomanut Street
Netanya, 4250445, Israel
Tel: +972-52-8998865
Fax: +972-72-2210752
E-mail: ophirl@tytocare.com

Date Prepared:

October 6, 2016

Trade Name:

Tyto Stethoscope

Classification Name:

Electronic stethoscope

Product Code:

DQD

Device Class:

II

Regulation Number:

870.1875

Panel:

Cardiovascular

Predicate Devices:

- PCP PC Stethoscope [RNK Products, Inc.] cleared under K102893
- 3M Littmann 3200 Stethoscope [3M Health Care] cleared under K083903

Intended Use / 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 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 by professional users in a clinical environment or in conjunction with patients or lay users in a non-clinical environment.

Device Description:
The Tyto Stethoscope 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 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:
The Tyto Stethoscope, like its two predicate devices, is an electronic stethoscope intended for projecting the sounds associated with the heart, lungs, arteries, veins, and other internal organs. Both the Tyto Stethoscope and the PCP PC Stethoscope are intended also to transmit the recorded auscultation sounds to a remote location where a clinician can listen to them. In addition, both these devices are indicated for use by lay users as well as by professional users.

The Tyto Stethoscope shares with its predicate devices similar structural design (i.e., device components and additional operational elements). In addition, similar principles and mode of operation are used:

- Both the Tyto Stethoscope and the PCP PC Stethoscope detect auscultation using a piezo sensor
- Both the Tyto Stethoscope and the Littmann Stethoscope use Bell and Diaphragm filters
- All three devices detect a comparable frequency range
- Data transfer is enabled on-line by all three devices and a store-and-forward mode is enabled by both the Tyto and Littmann Stethoscopes.

Performance Testing:
Performance testing was conducted in order to demonstrate the performance, safety and usability of the Tyto Stethoscope. The testing plan included the following main tests:

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

Test results indicated that the Tyto Stethoscope 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 is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.