March 14, 2023

Heartbuds LLC
% Michelle Lott
Principal and Founder
leanRAQA
2081 Longden Circle
Los Altos, California 94024

Re: K212906
Trade/Device Name: HeartBuds Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: March 7, 2023
Received: March 8, 2023

Dear Sheila Pickering:

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,

Robert T. Kazmierski -S

for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K212906

Device Name
HeartBuds Stethoscope

Indications for Use *(Describe)*
The HeartBuds Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location via the HeartBuds mobile application can listen to the auscultation sounds of a patient at a different location. The HeartBuds Stethoscope is intended to be used by professional users in a clinical environment or by non medical professional adult users in a non clinical 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.

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

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HeartBuds Electronic Stethoscope
K212906 510(k) Summary
Prepared August 11 2022

Sponsor: HeartBuds LLC
711 London Road
Winter Park, Florida 32792

Contact Person: Seth Ellis

Telephone: 407 906 2484

Submission Date: August 10, 2022

Device Name: HeartBuds Electronic Stethoscope

Common Name: Electronic Stethoscope

Trade Name: HeartBuds Model 1

Classification:
Regulatory Class: II
Review Category: 21 CFR 870.1875 (DQD)

Classification Panel: Cardiovascular diagnostics

A. Legally Marketed Predicate Devices

The predicate device is the Tyto Stethoscope (K181612).

B. Device Description:

HeartBuds is an electronic stethoscope intended to auscultate heart and lung sounds. HeartBuds Stethoscope can be used on any patient undergoing a physical assessment. This stethoscope consists of a hand-held device with integral plastic sound diaphragm, that must be used together with a smartphone equipped with the HeartBuds application software. HeartBuds Stethoscope allows users to digitally record heart and lung internal auscultation and transmit the sound data to a medical professional in another location. The HeartBuds system includes two (2) main components: The HeartBuds Electronic Stethoscope and the HeartBuds mobile app.

The HeartBuds Electronic Stethoscope connects to mobile devices (Apple and Android) by means of an audio cable. The HeartBuds app with the integrated HeartBuds software provides users a platform to listen, display, and record sounds simultaneously using an external microphone. The users can share their recordings with their healthcare provider within the HeartBuds app for remote examination

C. Intended Use / Indications for Use

The HeartBuds Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location via the HeartBuds mobile application can listen to the auscultation sounds of a patient at a different location. The HeartBuds Stethoscope is intended to be used by professional users in a clinical environment or by non medical professional adult users in a non clinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis

D. Substantial Equivalence

The HeartBuds electronic stethoscope (HeartBuds) is substantially equivalent to the Tyto Stethoscope manufactured by Tyto Care Ltd. and cleared pursuant to 510(k) premarket notification K181612. Both are portable hand-held devices intended to enable transmission of auscultation sound data. A detailed comparison of the HeartBuds device and the predicate is presented in the Table below.

Substantial Equivalence Table

#	Parameters	Subject Device	Predicate Device Tyto Stethoscope (K181612)	Substantially Equivalent (SE)
1	**Trade Name**	HeartBuds	Tyto Stethoscope	N/A
2	**Manufacturer**	HeartBuds LLC	Tyto Care Ltd.	N/A
3	**Classification**	Class II	Class II	Same
4	**Regulation No.**	21 CFR 870.1875	21 CFR 870.1875	Same
5	**Product Code(s)**	DQD	DQD	Same
6	**Indications for use**	The HeartBuds Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location via the HeartBuds mobile application can listen to the auscultation sounds of a patient at a different location. The HeartBuds 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.	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	SE

			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.	
7	**Device Description**	The HeartBuds Stethoscope when connected to the HeartBuds App, captures sounds by the HeartBuds Stethoscope which can be recorded by the App and stored to the cloud for future use. The HeartBuds mobile application on the smartphone records those sounds as an audio recording to be stored and if desired by the user to be shared with a healthcare provider. The HeartBuds App requires a user to register and create a secure login in order to provide a means to associate the recordings to each individual user and to be stored in the cloud (Google application Firebase). The HeartBuds App provides the capability to start and stop recording at the user's discretion. The HeartBuds App also provides the capability for the user to sample the sounds received from the HeartBuds Stethoscope before starting a recording. This provides a means for the user to either change the position of the Stethoscope to ensure the recording includes sounds of the heart or lung. The user stops the recording, the HeartBuds App names the file to facilitate future identification (both the user and a specific anatomical location) and loads it to the	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	SE

		cloud for storage. The HeartBuds App provides the user a list of all saved recordings. From the list of recordings the user can select one for replaying or to share via email.	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	
8	**Intended users**	Health care professionals and adult lay users (i.e., users who are not health care professionals)	professional as well as lay users in clinical or nonclinical environments	SE

9	**Intended Use Environments**	clinical or non-clinical environments	clinical or non-clinical environments	Same
10	**Types of stethoscope exams**	Heart, Lungs, and Audio	Heart, Lungs, Heart Rate and Audio	SE
11	**Functional elements**	stethoscope A mobile device (e.g., a smartphone, not part of the HeartBuds Stethoscope device, not supplied by HeartBuds, on which the proprietary HeartBuds App is running),	stethoscope 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), 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). 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).	SE
12	**Hardware and software platforms**	Android and iOS	Android and iOS	Same
13	**Dimensions**	2.0 x 1.7 x 1.375 inches HeartBuds Stethoscope only	3.35 x 2.87 x 1.85 inch (85 x 73 x 47mm)	SE
14	**Weight**	1.44 ounces (41 grams) HeartBuds Stethoscope only	0.33 lbs. (0.15kg)	SE
15	**Display**	No Display	2.4" LCD touch screen	SE
16	**Audio Output Port**	USB-C connection with audio jack adaptor provided by the phone manufacturer or only an audio jack if the smart device.	Standard 3.5mm headphone connector	SE
17	**Audio output method**	Headphone or audio recording	Audio recording	SE
18	**Power Output**	No power output	Proprietary plug, 5Vdc, 2.0A	SE
19	**Frequency range**	50 – 3000 Hz	20 - 3,500 Hz	SE

20	**Audio Output**	A recording playback on the smartphone.	3.5mm standard headphone connector	SE
21	**Battery**	No battery provided	Li-ion, built-in, rechargeable	SE
22	**Typical Battery life**	No battery provided.	Up to 400 cycles of charge/discharge	SE
23	**Dimensions**	2.0 x 1.7 x 1.375 inches HeartBuds Stethoscope only	1.57 x 1.53 inch (40 x 39 mm)	SE
24	**Weight**	1.44 ounces (41 grams) HeartBuds Stethoscope only	0.13 lbs. (0.06kg)	SE
25	**Operational flows/Method of transmitting recording to physician**	Cloud stored and forward by the user by email.	store-and forward flow and on-line exam flow	SE
26	**Operating Environment**	Temp range: 5°C - 40°C Humidity range: 15%- 90% (non-condensing) Pressure: 700 hPa to 1060 hPa	5° – 40°C (41° - 104°F) 15 - 70% (non-condensing) 700hPa to 1060hPa	SE
27	**Communication**	Wired	Wireless	SE
28	**Connections**	A wire connected to the smartphone audio jack	Information Not Available in product labeling	SE
29	**Permits data transfer of stored digital signals**	Yes	Yes	Same
30	**Signal storage**	Yes, virtually in the cloud	Yes	Same
31	**Diaphragm diameter**	1.45 inch diameter	Information Not Available in product labeling	
32	**User interface**	Smartphone device display	Smartphone device display	Same
33	**Amplification**	Amplification by the smart phone volume control	Information Not Available in product labeling	
34	**Waterproof**	No	No	Same
35	**Patient contacting materials**	Compliant with ISO 10993	Materials information not available; Compliant with ISO 10993	Same

36	**Electrical Safety**	Compliant with ANSI/AMMI 60601-1 and IEC 60601-1-2	Compliant with ANSI/AMMI 60601-1 and 60601-1-2	Same
37	**Usability**	Compliant with ISO 62366	Compliant with ISO 62366	Same

Discussion of Similarities and Differences

Summary of Similar Technological Characteristics.
The HeartBuds electronic stethoscope and the predicate are both electronic stethoscopes intended for projecting the sounds associated with vibrations or sounds of the human body. Therefore, they have the same intended use and core technology,
Both the Tyto Stethoscope and the HeartBuds Stethoscope are intended 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 adult lay users (i.e., adults who are not health care professionals).

As shown in the table above, the HeartBuds Stethoscope shares with its predicate device similar structural design and similar principles and mode of operation as follows:

1. The indications for use is similar with the subject device having fewer capabilities for data collection and processing.
2. The core technology is the same, although the predicate utilizes wireless communications
3. The classification code is the same
4. Both devices are indicated for OTC devices that can be used in the home as well as in a clinical environment.
5. Both devices are compliant with relevant safety standards (see performance data in this submission for ISO 10993, IEC 60601-1, IEC 60601-1-2 and ISO 62366)
6. Both devices use downloadable Apps for Android and iOS
7. Both the HeartBuds Stethoscope and the Tyto Stethoscope record auscultation
8. Both the HeartBuds Stethoscope and the Tyto Stethoscope store the recording on smart phone storage
9. Both the HeartBuds Stethoscope and the Tyto Stethoscope allow the user to share the recording
10. Both the HeartBuds Stethoscope and the Tyto Stethoscope provide a transfer of the recording to on-line applications (via email, cloud storage)

Summary of Different Technological Characteristics.
As shown in the table above, the HeartBuds Stethoscope has some differences from the predicate device. Where these differences exist, performance data is provided in this submission to demonstrate that the differences do not raise any new issues of safety or effectiveness.

1. The HeartBuds device has more limited capabilities than the Tyto device as listed in the table above. Because there are fewer capabilities there are fewer risks associated with the correct delivery of information to the health care professional who will review the device output.
2. Information on the specific materials used for the predicate are not available but are ISO 10993 compliant. Therefore, although the materials are not the same, both are substantially equivalent in that they are both compliant with ISO 10993.

3. The HeartBuds device is wired whereas the Tyto device is wireless so that wireless transmission protocols were not required as part of the performance data provided in this submission.
4. The software application is different in the HeartBuds and the Tyto device each using proprietary software algorithms. Details of the predicate software design are not available. However, the subject device software has been formally verified and validated according to the company's
5. Design Control process (see performance data provided in the software information sections)
6. There is no information available regarding cybersecurity protections in the predicate device. However, cybersecurity controls have been incorporated in the subject device and supporting data provided in the software information sections of this submission.

Discussion of Similarities and Differences

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30. Successful results for the following tests are included in the submission as performance data supporting substantial equivalence:

1. Bench testing for electrical and mechanical safety in compliance with applicable standards
2. Software testing, consisted of verification and validation testing, including test cases related to off the shelf software, as well as cybersecurity features.
3. Human factors testing to demonstrate usability in a simulated use environment when used by health care professionals and lay users.

Based on the comparison of indication for use and technological characteristics, the subject device is substantially equivalent to the predicate device. Based on the performance data provided in the submission the differences do not introduce new issues related to safety and efficacy.

E. Performance Data

Every specification of the HeartBuds Electronic Stethoscope has been verified and validated as required by the risk analysis. All design verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

The verification and validation testing included testing to the following applicable standards:

ISO 14971	Application of risk management to medical devices
ANSI/AAMI 60601-1	Medical electrical equipment- General requirements for basic safety and essential performance
IEC 60601-1-2	Electromagnetic disturbances
IEC 62366-1	Application of usability engineering to medical devices
ISO 10993	ISO 10993 5 ed, 2018, Biological evaluation of medical devices- Part 1 Evaluation and testing within a risk management process

Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30. Successful results for the following tests were included in the submission as performance data supporting substantial equivalence:

1. Bench testing for electrical and mechanical safety in compliance with the standards cited above.
2. Software testing, consisted of verification and validation testing, including test cases related to off the shelf software, as well as cybersecurity features.
3. Human factors testing to demonstrate usability in a simulated use environment when used by health care professionals and lay users.

Clinical data was not required for this type of device.

F. Conclusion

Potential risks were identified according to the ISO 14971 and ISO 62366 Standards. The risks were analyzed with regard to risk/benefit category and mitigations were implemented and tested as part of the performance testing described above. All risk mitigations were satisfactorily verified and validated. Where there were technological differences from the predicate, these were shown not to result in any new issues of safety or efficacy according to the performance data submitted.

Therefore, the HeartBuds Electronic Stethoscope is substantially equivalent to the predicate device with regards to intended use and technological characteristics. Results of performance testing demonstrated that the device met the design requirements and as well as the user needs.