February 8, 2019

Coala Life AB
% Pierre Bounaud
Senior Regulatory Specialist
Acknowledge Regulatory Strategies
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K182040
Trade/Device Name: Coala Heart Monitor
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH, DPS, DQD, DQC
Dated: February 1, 2019
Received: February 4, 2019

Dear Pierre Bounaud:

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,

Arielle Drummond -S

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)*
K182040

Device Name
Coala Heart Monitor

Indications for Use *(Describe)*
The Coala Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms and heart sound. The Coala Heart Monitor also displays ECG rhythms and detects the presence of normal sinus rhythm and atrial fibrillation (when prescribed or used under the care of a physician). The Coala Heart Monitor is intended for use by healthcare professionals and adults with known or suspected heart conditions.
Rx ONLY.

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
K182040

DATE PREPARED
February 1, 2019

MANUFACTURER AND 510(k) OWNER
Coala Life AB
Riddargatan 18
Telephone: + 46 70 7906734
Official Contact: Philip Siberg, CEO

REPRESENTATIVE/CONSULTANT
Pierre Bounaud, Ph.D.
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: pbounaud@acknowledge-rs.com

PROPRIETARY NAME OF SUBJECT DEVICE
Coala Heart Monitor

COMMON NAME
ECG Monitor

DEVICE CLASSIFICATION

Telephone electrocardiograph transmitter and receiver	21 CFR 870.2920	Class II	DXH
Electrocardiograph	21 CFR 870.2340	Class II	DPS
Stethoscope	21 CFR 870.1875	Class II	DQD
Phonocardiograph	21 CFR 870.2390	Class I	DQC

PREMARKET REVIEW
ODE/Division of Cardiovascular Devices (DCD)/Cardiac Diagnostics Devices Branch (CDDB)
Cardiovascular review panel

PREDICATE DEVICE IDENTIFICATION
The Coala Heart Monitor is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K142743	AliveCor Heart Monitor / AliveCor, Inc.	✓
K170874	Eko Model E5 / Eko Devices, Inc.	
K083903	3M Littmann Electronic Stethoscope, Model 3200 / 3M Company	

DEVICE DESCRIPTION

The Coala Heart Monitor is a medical device system that can be used by healthcare professionals for electrocardiogram (ECG) and digital auscultation (stethoscope) recordings. Persons with known or suspected heart conditions can use the Coala Heart Monitor to record ECG and heart sounds simultaneously for detection of normal sinus rhythm (NSR) and atrial fibrillation (AF) and to make these recordings available to their physician.

INDICATIONS FOR USE

The Coala Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms and heart sound. The Coala Heart Monitor also displays ECG rhythms and detects the presence of normal sinus rhythm and atrial fibrillation (when prescribed or used under the care of a physician). The Coala Heart Monitor is intended for use by healthcare professionals and adults with known or suspected heart conditions.
Rx ONLY.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has a similar design and dimensions, and uses similar materials (stainless steel electrodes, plastic body) as the devices cleared in K142743 and K170874. The subject device has equivalent general intended use and similar technological characteristics (ECG recordings) as the device cleared in K142743. The subject device has similar technological characteristics (ECG recordings or heart sound recordings) as the devices cleared in K170874 and K083903.

Unlike the predicate device cleared in K142743, the Coala Heart Monitor is prescription use only and uses a combination of chest and thumb recordings for ECG rhythms detection, with an additional electrode for noise suppression. It features a wider ECG sampling frequency, higher sample rate, higher ECG resolution, and the ECG recording length is fixed to 30 seconds. It also allows simultaneous heart sound recordings. The Coala Heart Monitor functions on a rechargeable battery and recordings are transferred via Bluetooth technology. The accompanying mobile app includes a messaging system for communication with a physician.

Unlike the predicate device cleared in K170874, the Coala Heart Monitor is intended for adults only and uses a combination of chest and thumb recordings for ECG rhythms detection, with an additional electrode for noise suppression. It features a wider ECG sampling frequency, the ECG recording length is fixed to 30 seconds, and the stethoscope frequency range is narrower. The accompanying mobile app communicates with a cloud server for recording analysis and storage, and it includes a messaging system for communication with a physician.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Coala Heart Monitor. The following non-clinical tests were performed in order to demonstrate safety based on current industry standards:

- Shelf life
- Biocompatibility Risk Assessment per ISO 10993-1
- Cytotoxicity testing per ISO 10993-5
- Irritation and sensitization testing per ISO 10993-10
- Chemical characterization per ISO 10993-18
- Software per AAMI/ANSI/IEC 62304
- Cybersecurity
- Electrical safety per IEC 60601-1, ANSI/AAMI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, and IEC 62133
- Wireless coexistence testing
- Bench performance testing
- Stethoscope bench performance testing (frequency response, impulse response, amplification and maximum output sound level)
- Sound sensor validation in a blind A/B type study with 20 patients
- Usability testing per IEC 62366

The results of these tests indicate that the Coala Heart Monitor is substantially equivalent to the predicate devices.

ECG performance of the Coala Heart Monitor was demonstrated in a real-world study in which 1,000 ECG recordings taken from a diverse patient demographics of 150 patients (men, women, age 20-90, BMI<18.5 to BMI>30) were analyzed by the device and assigned a category (0: Unreadable, 1: Normal Sinus Rhythm, 2: Atrial Fibrillation, 99: Unclassified). The ECG recordings were derived from actual Coala users in Sweden, without any exclusions, training, control or influence, under a defined time period. The prevalence of cardiac conditions in the user population was unknown. The same recordings were analyzed manually by a cardiologist as the gold standard. Signal quality and accuracy for Atrial Fibrillation detection by the Coala Heart Monitor were found to be high, with 97.2% sensitivity and 94.6% specificity as compared to a trained cardiologist. Similarly, signal quality and accuracy for Normal Sinus Rhythm detection by the Coala Heart Monitor were also found to be high, with 96.5% sensitivity and 88.7% specificity as compared to a trained cardiologist.

CONCLUSION

Based on the testing performed, including biocompatibility, shelf life validation, software validation, cybersecurity, electrical safety, wireless coexistence validation, non-clinical performance testing (bench testing, stethoscope performance testing, sound sensor validation), and usability testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Coala Heart Monitor are assessed to be substantially equivalent to the predicate devices.