November 15, 2018

Samsung Strategy and Innovation Center (SSIC)
Matthew Wiggins, Ph.D.
Acting Mgr QA/RA & Senior Mgr Algorithms
3655 North First Street
San Jose, California 95134

Re: K181998
Trade/Device Name: CardioBand Event Recorder
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 25, 2018
Received: July 26, 2018

Dear Matthew Wiggins:

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,

Jessica E. Paulsen -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)*
K181998

Device Name
CardioBand Event Recorder

Indications for Use *(Describe)*
The CardioBand Event Recorder is indicated for use by adult patients, when prescribed by a physician, to record, display, store and transfer single-channel electrocardiogram (ECG) for rhythm interpretation.

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

[As Required by 21 CFR 807.92(c)]

Owner Information [As required by 807.92(a)(1)]	Eunsung Park, SSIC-DH VP, Engineering SAMSUNG STRATEGY & INNOVATION CENTER 3655 North First Street San Jose, CA 95134 (408) 544 - 5310 es001.park@samsung.com Contact: Matthew Wiggins, SSIC-DH Quality Assurance and Regulatory Affairs Contact phone number: (770) 596-1765 Contact email: m.wiggins@samsung.com Summary was prepared on 29-JUN-2018 and revised on 15-NOV-2018
Device Information [As required by 807.92(a)(2)]	Trade name – CARDIOBAND© EVENT RECORDER Common name - CardioBand Classification name – Quantitative Electrocardiographic Detector (21 CFR 870.2340, Product Code DPS)
Claiming Equivalence [As required by 807.92(a)(3)]	K171816 KardiaBand System

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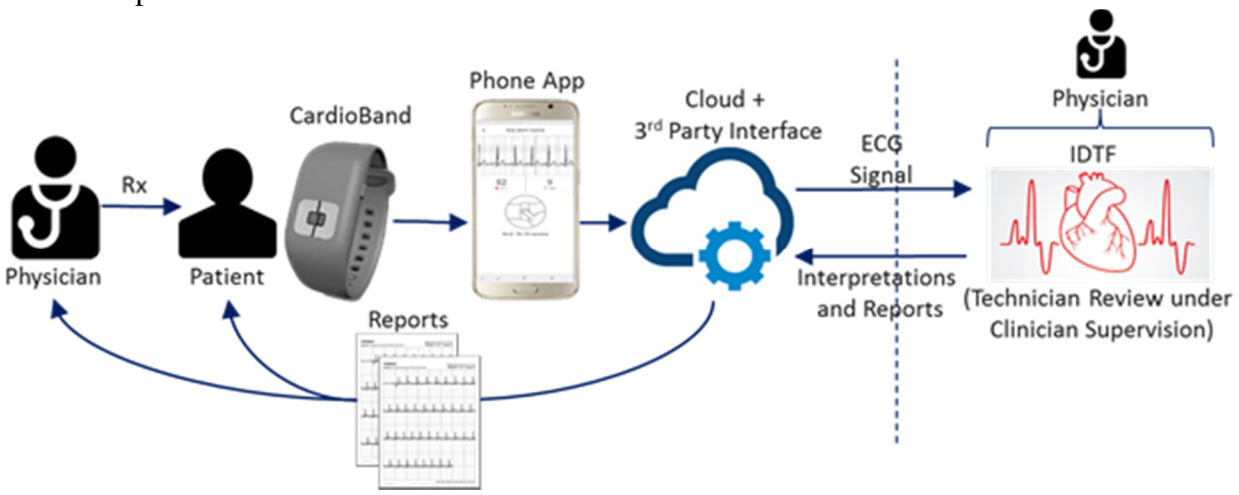
Device Description [As required by 807.92(a)(4)]	The Samsung CardioBand Event Recorder system allows for convenient acquisition of ECG from prescribed patients, allowing for the accurate assessment of the presence of arrhythmias by qualified healthcare providers. The system consists of three components (see Figure 1) including the wrist-worn CardioBand, a smart-phone application, and a secure cloud providing an interface to qualified healthcare providers, such as independent diagnostic testing facilities (IDTF) under clinician supervision.  Figure 1. Samsung CardioBand Event Recorder System Diagram The ECG signal is acquired with dry electrodes and the contact locations (wrist and finger) may contribute to noise. This noise can visually change the form of the ECG signal such that the measured PR, R-R, and QRS interval duration and QRS amplitude are less accurate than measurements from a 12 Lead diagnostic ECG monitor. The ECG signal acquired is intended to provide a screening, non-diagnostic ECG for use only by a qualified medical professional. It is intended for cardiac rhythm discrimination between Normal/AF/Abnormal.
Intended Use [As required by 807.92(a)(5)]	The CardioBand Event Recorder is intended to be used by a single patient to record, display, store and transfer single-channel electrocardiogram (ECG) for rhythm interpretation.

Predicate Device

[As required by 807.92(a)(6)]

Characteristic or Specification	*D1: AliveCor KardiaBand System K171816*	*D2: SSI CardioBand ECG Event Recorder*
Indications for Use	The KardiaBand System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The KardiaBand System also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician). The KardiaBand system is intended for use by healthcare professionals, adult patients with known or suspected heart conditions and health conscious individuals.	The CardioBand Event Recorder is indicated for use by adult patients, when prescribed by a physician, to record, display, store and transfer single-channel electrocardiogram (ECG) for rhythm interpretation.
Product code	DXH, DPS	DPS
Mechanism of Action	Users completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG	Same, except transmission to MCP is via Bluetooth LE
Anatomical Sites	Left hand fingers to right wrist or vice versa	Same
Where used (intended use)	Mobile/active users at rest (ambulatory)	Same

Data Acquisition: Frequency Response	0.5 Hz – 40 Hz	Same
ECG channels	Single Channel	Same
ECG Resolution	16 bit	24 bit
Sample Rate	300 Samples/ Second	500 Samples/ Second
Memory Capacity	Essentially unlimited due to real-time transmission to MCP memory	Same
Number of ECG Leads	Single Lead, 2 electrodes	Same
Energy Source: Battery Battery Life	Replaceable Lithium Manganese Dioxide coin cells 100 hours operation	Internal Lithium Ion battery 7 days operation
User Interface: Primary Lead	Lead 1: Left to Right	Same
Hardware platforms	Apple iPhone and Apple Watch Band Sensor	Samsung Galaxy S6 or S7 Phone and CardioBand Sensor
Software platforms	Apple iOS and Apple Watch OS	Android OS (versions Marshmallow to Nougat)
Physical Specifications: Dimensions Weight	24.5 x 24.5 x 6.5 mm 9 grams	35.6 x 25.5 x 11.8 mm 14.2 grams

Prescribed/Over-the-Counter	Prescription and OTC	Prescription only
Environmental: Operating Temp Storage Temp	 10 to 40 degrees C -20 to 60 degrees C	 -5 to 50 degrees C -20 to 30 degrees C
Communications	Ultrasonic Acoustics	Bluetooth LE
Conformance to Recognized Standards: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	(From FDA Database) IEC 60601-1 60601-1-2	(From Certification Labs) IEC 60601-1:2005 /(R)2012 and A1:2012 60601-1-2:2014

	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	60601-2-47	60601-2-47
	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	ISO 10993-1	ISO 10993-1
	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	ISO 10993-5	ISO 10993-5
	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	ISO 10993-10	ISO 10993-10
Non-Clinical Performance [As required by 807.92(b)(1)]	The CardioBand Event Recorder was tested in accordance with international recognized standards for EMC and electrical safety, and for biocompatibility. Further, the device underwent verification and validation testing for wireless coexistence and for various data integrity, and signal sufficiency.		

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Clinical Performance [As required by 807.92(b)(2)]	The CardioBand development team elected to validate the signal quality of the CardioBand ECG signal in a comparative, single-center, non-randomized study. The CardioBand was compared to the predicate device and to a reference gel-electrode 12-lead ECG device.
Conclusion on Clinical and Non-clinical Tests [As required by 807.92(b)(3)]	The CardioBand Event Recorder is substantially equivalent to the KardiaBand System (K171816). The devices have nearly identical intended use. The devices have the same key technological characteristics. The devices have the same mechanism of action, and they are similar in dimensional and other characteristics. The devices conform to the same recognized standards. In clinical testing, the CardioBand demonstrated that for quantitative ECG measurement analysis it was substantially equivalent to the predicate when compared to a gel-electrode reference ECG device given a margin of clinically acceptable measurement error.
Other Information As required by 807.92(d)]	