April 26, 2021

Xandar Kardian Inc.
℅ Brennan Sullivan
Official Correspondent
Alira Health
1 Grant Street
Suite 400
Framingham, Massachusetts 01702

Re: K202464
Trade/Device Name: Vital Sign Monitoring Sensor (Model: XK300)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT
Dated: March 24, 2021
Received: March 25, 2021

Dear Brennan Sullivan:

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,

Jennifer Shih Kozen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202464

Device Name
Common Name: Heart Rate and Respiration Rate Monitor
Classification Name: Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) & Monitor, Breathing Frequency
Trade Name: Vital Sign Monitoring Sensor (Model: XK300)

Indications for Use *(Describe)*
The Vital Sign Monitoring Sensor (Model XK300) is intended to measure heart rate and respiration rate in adult patients in a general care hospital environment including nursing homes. The Vital Sign Monitoring Sensor can be used for home healthcare for data collection to inform patient care but not to acutely treat a patient. XK300 monitors presence or absence of a patient in detection area of within 7 meters. The XK30 also monitors the length of continuous patient motion or absence of patient motion.

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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510(k) Summary
for the Xandar Kardian
Vital Signs Monitoring Sensor
(per 21CFR 807.XXX)

Date: August 26, 2020

1. 510K Applicant / Submitter:

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2. Submission Contact Person

Brennan Sullivan
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3. Subject Device

Trade Name: Vital Sign Monitoring Sensor (Model: XK300)
Classification Name: Monitor, Cardiac (incl Cardiotachometer & Rate Alarm) & Monitor, Breathing Frequency
Regulation Number: 21 CFR 872.2300 & 868.2375
Regulation Name: Heart Rate and Respiration Rate Monitor
Regulatory Class: II
Product Code: DRT & BZQ

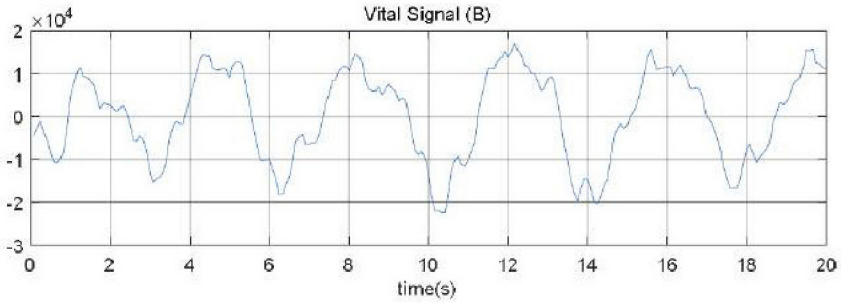
4. Predicate Device

Trade Name: Patient Assessment Monitor (PAM™3000)
510(k) Number: K082626
Classification Name: Monitor, Cardiac (incl Cardiotachometer & Rate Alarm) & Monitor, Breathing Frequency
Regulation Number: 21 CFR 872.2300 & 868.2375
Regulation Name: Heart Rate and Respiration Rate Monitor

Regulatory Class: II
Product Code: DRT & BZQ

5. Description:

The Vital Sign Monitoring Sensor (Model XK300) measures heart rate, respiratory rate (breathing rate), and movement of people with very little or no movement (rest mode) using Impulse Radio Ultra-Wideband (IR UWB) radar technology. The heart rate and respiratory rate are measured by detecting minute displacements of the chest and converting the movement into the number of breaths and heart beats per minute. Figure 5-1 is a representative graph produced by the Vital Sign Monitoring Sensor.



Signal from respiration and heartbeat measured by sensors

Figure 5-1

6. Indications for Use

The Vital Sign Monitoring Sensor (Model XK300) is intended to measure heart rate and respiration rate in adult patients in a general care hospital environment including nursing homes. The Vital Sign Monitoring Sensor can be used for home healthcare for data collection to inform patient care but not to acutely treat a patient. XK300 monitors presence or absence of a patient in a detection area of within 7 meters. The XK300 also monitors the length of continuous patient motion or absence of patient motion.

7. Substantial Equivalence Discussion:

The Vital Sign Monitoring Sensor (VSMS) (Model XK300) is substantially equivalent to the Wireless 2000 RF & UWB Technologies Ltd. Patient Assessment Monitor (PAM 3000) subject of K082626 in both indications for use and technological characteristics.

The Vital Sign Monitoring Sensor (Model XK300) has similiar indications for use as the predicate device in that they are both indicated to measure heart rate and respiration rate in adult patients in a general care hospital environment including, nursing homes. Both devices also monitor the presence or absence of a patient in bed (bed exit). Unlike the PAM 3000, the Vital Sign Monitoring System can also be used in a home to collect data but may not be used to acutely treat a patient. This additional indication is only used to inform treatment. The subject device and predicate device differ in heart rate measurement range and respiratory

measurement range in that the XK300 has a radius of up to 7 meters. However, performance testing has confirmed that this difference does not affect the performance of the Vital Signs Monitoring Sensor. Table 5-1 compares the indications for use and characteristics of Vital Signs Monitoring System with the predicate.

Table 5-1: Side by Side Comparison Table of Vital Sign Monitoring System with PAM3000

	Candidate Device	**Predicate Device**	**Comparison**
510(k) Number	K202464	K082626	-
Device Name	Vital Sign Monitoring Sensor (Model: XK300)	Patient Assessment Monitor (PAM™3000)	-
Common Name	Heart Rate and Respiration Rate Monitor	Heart Rate and Respiration Rate Monitor	-
Manufacturer	XANDAR KARDIAN INC.	Wireless 2000 RF & UWB Technologies Ltd.	-
Intended Use	The Vital Sign Monitoring Sensor (Model XK300) is intended to measure heart rate and respiration rate in adult patients in a general care hospital environment including nursing homes. The Vital Sign Monitoring Sensor can be used for home healthcare for data collection to inform patient care but not to acutely treat a patient. XK300 monitors the presence or absence of a patient in a detection area of within 7 meters. The XK300 also monitors the length of continuous patient motion or absence of patient motion.	The PAM™3000 system is intended to measure heart rate and respiration rate in adult patients, in a general care hospital environment including nursing homes. The system will also monitor presence or absence of a patient in bed (bed exit).	Same
Component	Sensor USB micro b cable	Bed Sensor Panel Repeater Base Stations Central Computer Station Central Base Station	Different
Patient Type	Adult	Adult	Same
Use Environment	General Care Hospital Environment including Nursing Homes	General Care Hospital Environment including Nursing Homes	Same
Heart Rate Measurement Range	60-120 beats per minute	Normal: 45-115 beats per minute Elevated: 85-170 beats per minute	Different
Respiratory Rate Measurement Range	6-55 breaths per minute	Normal: 3-30 breaths per minute Elevated: 3-50 breaths per minute	Different

8. Performance Tests (Non-clinical)

The following testing has been performed using the XK 300:

- IEC 60601-1:2005/A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010/A1:2013 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
- IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304:2006/A1:2015 Medical device software - Software life cycle processes
- IEC 60068-2-27:2008 Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
- IEC 60068-2-6:2007 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal)
- IEC 60068-2-34:2008/A1:2019 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance

In addition to the testing above, software validation and usability testing were also conducted. This testing showed that the XK300 performed and functioned as intended and according to the design specifications.

9. Conclusion:

Based on the information provided in this 510(k) premarket notification, Xandar Kardian Inc. concludes that the Vital Sign Monitoring Sensor (Model XK300) is substantially equivalent to the Patient Assessment Monitor (PAM™3000) (K082626) predicate device.