May 30, 2024

Circadia Technologies, Ltd.
Erhan Ilhan
Head of Quality and Regulatory
20 St Thomas Street
London, Greater London SE1 9RS
United Kingdom

Re: K234003
Trade/Device Name: The Circadia C200 System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, BZQ
Dated: May 1, 2024
Received: May 1, 2024

Dear Erhan Ilhan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 W. Shih -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234003

Device Name
The Circadia C200 System

Indications for Use *(Describe)*

The Circadia C200 System is intended for the measurement of respiratory rate and heart rate, including spot measurement.

The system is indicated for adult patients in clinical settings, such as skilled nursing and long-term care facilities.

The system is not indicated for active patient monitoring, and does not provide alarms for timely response in acute life-threatening situations. The system is not intended to monitor heart rate in patients with arrhythmias.

The system is intended to be used by healthcare professionals (HCPs) and data are intended to be reviewed by HCPs to inform patient care.

The system also monitors patient motion, and patient presence or absence near the device (exits).

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.

510(k) Summary

1.0 Submitter Information

Name:	Circadia Technologies, Ltd.
Address:	Runway East Borough Market 20 St. Thomas Street, London SE1 9RS United Kingdom
Contact Name:	Erhan Ilhan Head of Quality and Regulatory
Phone:	(800) 985-5596
Date Prepared	May 25, 2024

2.0 Subject Device

Trade Name:	The Circadia C200 System
Common Name:	Cardiac Monitor
Regulation Number:	21 CFR 870.2300
Class:	II
Product Code:	DRT, BZQ
Premarket Review:	OPEQ/OHT2A: Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Review Panel:	Cardiovascular

3.0 Predicate Device

Trade Name:	Vital Sign Monitoring Sensor (K202464)
Common Name:	Cardiac Monitor
Regulation Number:	21 CFR 870.2300
Class:	II
Product Code:	DRT, BZQ
Premarket Review:	OPEQ/OHT2A: Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
Review Panel:	Cardiovascular

4.0 Device Description

The Circadia C200 System is a contactless system that uses radar to monitor respiratory rate (RR), heart rate (HR), motion, and presence of a patient in its detection range. The System is designed to monitor a patient automatically, without the need for the patient to wear or do anything, or for a healthcare professional (HCP) to interact with the device. The System is thus suitable for long-term and unsupervised monitoring.

The System may also be used to obtain on-demand spot measurements of heart rate and respiratory rate. This allows HCPs to control the frequency and timing of these measurements using the C200 System.

The System consists of the Circadia Contactless Cardiorespiratory Monitor (the "Monitor"), the Circadia Cloud Service (the "Cloud Service"), and the Circadia Pro App (the "App").

The Monitor may be installed next to a patient's bedside. It uses a radar-based motion sensor to detect micromotions caused by ventilation and heartbeat, to measure a patient's RR and HR while the patient is in its detection range at rest. Data is processed continuously on the Monitor, and streamed to the Cloud Service over a Wi-Fi network.

The Cloud Service offers a set of Application Programming Interfaces (APIs) that allows the Monitor to connect to the server and send data over a secure channel. In addition, it allows for patient data to be retrieved from the App.

The App allows a healthcare professional to retrospectively review RR and HR data from multiple connected Monitors. Motion and presence/exit data are available in real time. The App operates from an Android tablet (not supplied, not included in the System). The App includes a functionality to notify a user if no HR has been obtained within the most recent 8 hours.

5.0 Indications for Use

The Circadia C200 System is intended for the measurement of respiratory rate and heart rate, including spot measurement.

The system is indicated for adult patients in clinical settings, such as skilled nursing and long-term care facilities.

The system is not indicated for active patient monitoring, and does not provide alarms for timely response in acute life-threatening situations. The system is not intended to monitor heart rate in patients with arrhythmias.

The system is intended to be used by healthcare professionals (HCPs) and data are intended to be reviewed by HCPs to inform patient care.

The system also monitors patient motion, and patient presence or absence near the device (exits).

6.0 Comparison to Predicate Device

The Circadia C200 System is substantially equivalent to the Vital Sign Monitoring Sensor (Model: XK300) predicate devices (K202464), based on similar intended use and

technological characteristics.

The subject device has the same intended use as the predicate device cleared in K202464 which is to contactlessly measure heart rate and respiration rate in adult patients in a clinical setting, such as skilled nursing and long-term care facilities. Additionally, the subject and predicate devices are intended to monitor motion in the detection range, and to monitor the presence or absence of a patient in the detection range. The subject device has similar technological characteristics to the device cleared in K202464. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates. Table 6-1 compares the indications for use and characteristics of the Circadia C200 system to the predicate.

Table 6-1: Comparison to the Predicate Device

Feature	**Subject Device: Circadia C200 System**	**Predicate Device: Vital Sign Monitoring Sensor (Model XK300)**	**Reference Device: Circadia C100 System**	**Comments**
510(k)	K234003	K202464	K200445	N/A
Decision date	N/A	26-APR-2021	24-JUN-2020	N/A
Product Name	Cardiac Monitor (Including Cardiotachometer And Rate Alarm)	Cardiac Monitor (Including Cardiotachometer And Rate Alarm)	Breathing Frequency Monitor	**Identical to Predicate**
Product Code	DRT, BZQ	DRT, BZQ	BZQ	**Identical to Predicate**
Intended Use	The intended use is to contactlessly measure heart rate and respiration rate and detect patient motion.	The intended use is to contactlessly measure heart rate and respiration rate and detect patient motion.	The intended use is to contactlessly measure respiratory rate.	**Identical to Predicate**

Indications for Use	The Circadia C200 System is intended for the measurement of respiratory rate and heart rate, including spot measurement. The system is indicated for adult patients in clinical settings, such as skilled nursing and long-term care facilities. The system is not indicated for active patient monitoring, and does not provide alarms for timely response in acute life-threatening situations. The system is not intended to monitor heart rate in patients with arrhythmias. The system is intended to be used by healthcare professionals (HCPs) and data are intended to be reviewed by HCPs to inform patient care. The system also monitors patient motion, and patient presence or absence near the device (exits).	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 Circadia C100 System is indicated for both contactless spot checking and continuous measurement of respiratory rate data as part of a vital signs assessment. The system records, transmits, and displays respiratory rate from multiple connected devices for retrospective analysis only. The system is intended to be used under the care of clinicians and medically qualified personnel. The system is indicated for use in adult patients during no-motion conditions, for patients in health care facilities. It is available for sale only upon the order of a physician or licensed health care provider. The Circadia C100 System is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations. It is not intended to monitor vital signs. This system is not an	**Similar to Predicate** The Subject device is not intended for use in the home environment.

			apnea monitor.	
Patient Type	Adult	Adult	Adult	**Identical to Predicate**
User Population	Healthcare Providers	Healthcare Providers	Healthcare Providers	**Identical to Predicate**
Environment	Healthcare facilities, including skilled nursing and long-term care facilities.	General Care Hospital Environment including Nursing Homes	Healthcare facilities	**Similar to Predicate**
Technology	Contactless, radar-based measurement of micro-motions	Contactless, radar-based measurement of micro-motions	Contactless, radar-based measurement of micro-motions	**Identical to Predicate**
Physiological phenomenon measured	Micro-motions of the skin, caused by ventilation and heartbeat	Micro-motions of the skin, caused by ventilation and heartbeat	Micro-motions of the skin, caused by ventilation and heartbeat	**Identical to Predicate**
Radar sensor	6.4 - 7.8 GHz UWB	6.4 - 7.8 GHz UWB	6.4 - 7.8 GHz UWB	**Identical to Predicate**
Contactless Monitoring	Yes	Yes	Yes	**Identical to Predicate**
Heart Range Measurement Range	40 – 140 beats per minute	60 – 120 beats per minute	N/A	**Similar to Predicate**
Respiratory Rate Measurement Range	7 - 38 breaths per minute	6 – 55 breaths per minute	7 – 38 breaths per minute	**Similar to Predicate and Identical to C100 Reference**
Detects Patient Motion, and Presence/ Absence	Yes	Yes	No	**Identical to Predicate**

7.0 Performance Data (Non-Clinical Testing)

The following tests were performed to demonstrate safety based on current industry standards:

- Software Verification and Validation (per IEC 62304:2006/Al:2015)
- Electrical Safety (per IEC 60601-1:2005)
- EMC Testing (per IEC 60601-1-2:2014)
- Wireless Testing (per IEEE C63.27-2017)
- Motion Validation
- Presence Validation
- HR Detectable Range Verification
- HR Acquisition Rate Verification
- Circadia Monitor Drop Test
- Circadia Monitor Power Cord/Button Fatigue Test

The results of these tests indicate that the Circadia C200 System is substantially equivalent to the predicate device.

8.0 Performance Data (Clinical Testing)

To evaluate the performance of the Circadia C200 System, heart rate (HR) and respiratory rate (RR) clinical validation was performed.

Clinical testing was performed to evaluate RR monitoring performance, using the Circadia C100 System (reference device, K200445), which has identical hardware and RR monitoring functionality as the subject device. Clinical testing demonstrated that RR monitoring performance of the subject device was equivalent to the reference device.

Clinical testing was performed to evaluate HR monitoring performance, in two separate studies, by comparing subject device HR to gold standard reference HR (obtained using reference device K182030). Performance was assessed in clinical populations (n=49 and n=41 patients, for studies 1 and 2, respectively) and use cases representative of the subject device indications for use. Agreement with the gold standard was found to meet the pre-specified acceptance criteria of ± 5 BPM. Clinical testing demonstrated that HR monitoring performance of the subject device was equivalent to the predicate device. Subject demographics and baseline characteristics for both studies can be found in Table 8-1.

Table 8-1: Subject baseline demographics

Characteristic	Study 1, N=49	Study 2, N=41	Total, N=90
Age [years]			
Range	33 - 92	27 - 88	27 - 92
Median (interquartile range)	75 (11)	72 (12)	73 (14)
Gender [N (%)]			
Female	27 (55%)	21 (51%)	48 (53%)
Male	22 (45%)	20 (49%)	42 (47%)
Body-mass index [kg/m²]			
Range	17 - 73	15 - 56	15 - 73
Median (interquartile range)	32 (11)	27 (8)	28 (12)
Race [N (%)]			
American Indian or Alaska Native	-	1 (2%)	1 (1%)
Asian	2 (4%)	1 (2%)	3 (3%)
Black or African American	7 (14%)	13 (32%)	20 (22%)
White	40 (82%)	23 (56%)	63 (70%)
More than one race	-	3 (7%)	3 (3%)
Ethnicity [N (%)]			
Hispanic or Latino	6 (12%)	6 (15%)	12 (13%)
Not Hispanic or Latino	43 (88%)	35 (85%)	78 (87%)

N, number; kg, kilogram; m, meter.

9.0 Warnings and Important Use Conditions

The C200 System is not intended to monitor heart rate in patients with arrhythmias, such as atrial fibrillation. Use within this patient population will likely result in reduced performance.

For optimal heart rate monitoring performance, the C200 System Monitor is intended to be used to the side of the patient, and should be positioned 1.0 meter (3.0 feet) or less from the patient.

10.0 Conclusion

The Circadia C200 System is substantially equivalent to the predicate device based on the testing performed, the same intended use and similar indications, technological characteristics and principles of operation. The differences between the devices have been properly evaluated through the software verification and validation, bench test validation, and clinical validation, and do not present any new issues of safety or effectiveness. Thus, the Circadia C200 System was determined to be substantially equivalent to the predicate devices.