February 3, 2026

Circadia Health, Inc.
Timo Lauteslager
Chief Science & Integrity Officer
507 S Douglas St.
El Segundo, California 90245

Re: K252676
Trade/Device Name: The Circadia C300 System (C300)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, BZQ
Dated: December 4, 2025
Received: December 4, 2025

Dear Timo Lauteslager:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252676

Device Name
The Circadia C300 System (C300)

Indications for Use *(Describe)*
The Circadia C300 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.

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

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510(k) Summary

1.0 Submitter Information

Applicant Name:	Circadia Health, Inc.
Applicant Address:	507 S Douglas St, El Segundo, CA 90245 USA
Applicant Contact:	Timo Lauteslager Chief Scientist timo@circadia.health (800) 985-5596
Correspondent Contact:	Erhan Ilhan Head of Quality and Regulatory erhan@circadia.health (800) 985-5596
Date Prepared	January 28, 2026

2.0 Subject Device

Trade Name:	The Circadia C300 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:	The Circadia C200 System (K234003)
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 C300 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 HR and RR. This allows HCPs to control the frequency and timing of these measurements using the Circadia C300 System.

The System consists of the Circadia Contactless Cardiorespiratory Monitor (the "Monitor"), the Circadia Cloud Service (the "Cloud Service"), and the Circadia Clinical Intelligence Platform (CIP) Application (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 iOS device (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 C300 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 C300 System is substantially equivalent to the Circadia C200 System predicate device (K234003), based on identical intended use and similar technological characteristics.

The subject device has the same intended use as the predicate device cleared in K234003 which is to contactlessly measure heart rate (HR) and respiration rate (RR) 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 C300 System includes several component level updates compared to the C200 System, including replacement of the radar module, corresponding radar driver updates, minor hardware changes for supply continuity, and software updates associated with integrating the updated radar module. The C300 System uses an FMCW radar with center frequency of 59.8 GHz, compared to an UWB radar with 7.3 GHz center frequency for the predicate C200 System. However, both devices use the same fundamental contactless radar-based sensing principle to detect micromotions associated with respiration and cardiac activity. These updates do not change the intended use, indications for use, physiological output parameters, sensing principle, or overall technological characteristics.

All modifications underwent full software verification and validation, bench and clinical performance testing, as well as EMC testing and electrical safety testing. Testing demonstrates that the modifications do not raise new questions of safety or effectiveness when compared to the predicate device.

Table 6-1 compares the indications for use and technological characteristics of the Circadia C300 System and the predicate device.

Table 6-1: Comparison to the Predicate Device

Feature	Subject Device: Circadia C300 System	Predicate Device: Circadia C200 System	Comments
510(k)	K252676	K234003	N/A
Decision date	February 2026	May 2024	N/A
Product Name	Cardiac Monitor (Including Cardiotachometer And Rate Alarm)	Cardiac Monitor (Including Cardiotachometer And Rate Alarm)	Identical to Predicate
Product Code	DRT, BZQ	DRT, 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.	Identical to Predicate

Indications for Use	The Circadia C300 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 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).	Identical to Predicate
Patient Type	Adult	Adult	Identical to Predicate
User Population	Healthcare Providers	Healthcare Providers	Identical to Predicate
Environment	Healthcare facilities, including skilled nursing and long-term care facilities.	Healthcare facilities, including skilled nursing and long-term care facilities.	Identical to Predicate
Technology	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	Identical to Predicate
Radar sensor	58.0 - 61.5 GHz FMCW	6.4 - 7.8 GHz UWB	Different to Predicate. The subject device uses a different radar type and

			frequency band to detect the same physiological micromotions (respiration and cardiac). This does not alter the principle of operation or the measured parameters. Testing has shown that the increased bandwidth and center frequency improve measurement performance.
Respiratory Rate Measurement Range	7 - 38 breaths per minute	7 - 38 breaths per minute	Identical to Predicate
Heart Rate Measurement Range	40 - 140 beats per minute	40 - 140 beats per minute	Identical to Predicate
Detects Patient Motion, and Presence/ Absence	Yes	Yes	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 Testing (per IEC 60601-1:2005 + A1:2012 + A2:2020)
- EMC Testing (per IEC 60601-1-2:2014 + A1:2020)
- EMC Testing (per AIM 7351731 Rev. 3.00 (2021-06-04)
- EMC Testing (Common EM emitters and 5G, per 2022 FDA Guidance *"Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff")*
- Wireless Coexistence Testing (per IEEE/ANSI C63.27-2021)
- RR and HR Detectable Range Verification
- RR and HR Confounding Factors Verification

The results of these tests indicate that the Circadia C300 System is substantially equivalent to the predicate device.

8.0 Performance Data (Clinical Testing)

Clinical testing was conducted to evaluate RR and HR monitoring performance by comparing subject device outputs to gold standard reference data (devices K150272 and K182030, for RR and HR respectively). Testing was performed in a representative clinical population under use conditions consistent with the subject device's indications for use. Performance was evaluated during controlled monitoring conditions (n = 45 subjects) as well as during uncontrolled monitoring conditions (n = 40 subjects). For all conditions, agreement with the reference met the pre-specified acceptance criteria of ±5 beats per minute for HR. The C300 Monitor demonstrated RR accuracy (ARMS) within ±3 breaths per minute, across all tested conditions. Results demonstrated that the subject device provides RR and HR monitoring performance equivalent to the predicate device. Study sample demographics are summarized in Table 8-1.

Table 8-1: Patient Demographics and Baseline Characteristics

Characteristic	Property	Controlled Condition (n=45)	Uncontrolled Condition (n=40)
Age [years]	Range	28 - 93	46 - 93
	Median (interquartile range)	73 (13.0)	76 (14.0)
Gender	Female [N (%)]	22 (48.9%)	22 (55.0%)
	Male [N (%)]	23 (51.1%)	18 (45.0%)
Body-mass index [kg/m²]	Range	19.3 - 41.8	17.2 - 42.1
	Median (interquartile range)	27.4 (8.4)	26.5 (8.7)
Race	American Indian or Alaska Native [N (%)]	1 (2.2%)	0 (0%)
	Asian [N (%)]	1 (2.2%)	2 (5.0%)
	Black or African American [N (%)]	11 (24.4%)	12 (30.0%)
	White [N (%)]	32 (71.1%)	26 (65.0%)
Ethnicity	Hispanic or Latino [N (%)]	6 (13.3%)	6 (15.0%)

	Not Hispanic or Latino [N (%)]	39 (86.7%)	34 (85.0%)

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

9.0 Warnings and Important Use Conditions

The Circadia C300 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 Circadia C300 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 C300 System is substantially equivalent to the predicate device based on testing performed, identical intended use and indications for use, similar technological characteristics, and identical principles of operation. Differences between the devices were fully evaluated through software verification and validation, bench testing, and clinical validation, and do not raise new questions of safety or effectiveness. As such, the Circadia C300 System is determined to be substantially equivalent to the predicate device.