June 24, 2020

Circadia Technologies Ltd.
℅ Andrew Wu
Software Consultant
Rook Quality Systems, LLC.
1155 Mount Vernon Highway, Suite 800
Dunwoody, Georgia 30338

Re: K200445
Trade/Device Name: The Circadia C100 System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: May 4, 2020
Received: May 7, 2020

Dear Andrew Wu:

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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K200445

Device Name
The Circadia C100 System

Indications for Use *(Describe)*
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 apnea monitor

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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The Circadia C100 System 510(K) Summary

Date Prepared June 19, 2020

Manufacturer and 510(k) Owner

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Device Information

Proprietary Name: The Circadia C100 System

Trade Name: The Circadia C100 System

Classification Name: Monitor, Breathing Frequency

Regulation Number 21 CFR 868.2375

Product Code(s) BZQ

Classification II

Review Panel Anesthesiology

Use Prescription

Indications for Use

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 apnea monitor.

Device Description

The Circadia C100 System consists of three components:

- "The Monitor" - Circadia Contactless Breathing Monitor: The Monitor is a contact-less breathing monitor placed at a bedside table. The Monitor records respiratory rate of adult patients in hospitals and clinical settings (e.g. post-acute care settings such as General Care Floors (GCF), Inpatient Rehabilitation Facilities (IRF), and Skilled Nursing Facilities (SNF)). The Monitor utilizes a UWB-based (Ultra-Wideband based) motion sensor to detect the movement of the abdomen and the chest to derive respiratory data.
- "The App" - Circadia Pro Android App: The App allows Technical Support Staff to setup and configure monitors and allows Clinical Staff to review data collected by the monitors. The App is operated from the central “hub” of a ward or nursing station to monitor data collected by multiple monitors for retrospective analysis only, not for active patient monitoring. The App operates from an Android tablet and uses a USB-C connection for initial configuration. The App is designed to communicate with The Monitor and allow it to connect to a Wi-Fi network and subsequently, The Cloud Service.
- "The Cloud Service" - Circadia Cloud Service: The Cloud Service offers a set of APIs that allows the monitor to connect to server, send respiratory data over a secure channel, and allows the monitor to track Clinical Staff’s personal data and the patient's respiratory data.

Predicate Device Identification

The Circadia C100 System is substantially equivalent to the SleepMinder Breathing Frequency Indicator (model BM07) from BiancaMed Ltd (K103631).

The Circadia C100 System has the same intended use and similar indications, technological characteristics, and principles of operation to the device cleared in K103631. Therefore, K103631 is listed as the primary predicate device for The Circadia C100 System. EMBLETTA MPR from EMBLA SYSTEMS (K122516) is listed as a reference device.

Equivalence to Predicate Device

The subject device has the same intended use and similar technological characteristics (e.g. pulsed radar as its sensor technology to monitor respiratory rate) to the device cleared in K103631.

- Technological Characteristics: The Circadia C100 System utilizes a 6.394 to 7.844GHz pulsed radar as its sensor technology, in comparison to 5.8GHz pulsed radar in the device cleared in K103631. Leveraging the similar rationale in K103631, both frequencies are in common use as radiolocation frequencies and are in license-free portions of the electromagnetic spectrum. The choice of center frequency and pulsed are merely design decisions. Both the subject device and predicate device are contactless respiratory monitors intended to be placed on desk top adjacent to a patient being measured. Both the subject device and predicate device utilize attenuation of the reflected radio signal to measure the chest movement of a patient for respiratory monitoring. Non-clinical testing was carried out to verify that the safety and effectiveness of the subject device is substantially equivalent to the predicate device based on the aforementioned technological characteristics of the subject device. Hence, there are no significant differences in the technological characteristics between the subject device and primary predicate device.

	Subject Device	**Primary Predicate**	**Reference Device**
Product Name	**The Circadia C100 System from Circadia Technologies Ltd (K200445)**	**SleepMinder Breathing Frequency Indicator (model BM07) from BiancaMed Ltd (K103631)**	**EMBLETTA MPR from EMBLA SYSTEMS (K122516)**
Product Code	BZQ	BZQ	MNR
Primary Output	Displays respiratory rate.	Displays respiratory rate	Respiratory rate and heart rate.
Intended Use	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	The device is intended to be used for the spot measurement of respiration rate of an adult patient in a hospital and clinical setting. It is not a vital signs monitor or an apnea monitor. The device is indicated for use as suitable for	The Embletta MPR is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The Embletta MPR records multiple physiological parameters from a

	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 apnea monitor.	use on adult patients. It should not be used on patients that exhibit uncontrolled limb movement.	sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep-related medical disorders by trained personnel. The Embletta MPR is intended to be used for adult and pediatric (excluding neonatal and infant) studies. The device is not equipped with alarms and is not intended to be used as a monitor. The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort. The device does not monitor or diagnose the patient and does not issue any alarms.
Intended Use Environment	Hospital post-acute care settings such as General Care Floors (GCF), Inpatient Rehabilitation Facilities (IRF), and Skilled Nursing Facilities (SNF).	Hospital and clinical setting.	The general intended environments are hospitals, institutions, sleep centers, the home and sleep clinics or the patient's home.
Duration of Monitoring	Spot Check and Continuous Measurement	Spot Check	Sleep
Patient Interface	Non patient contacting,	Non patient contacting,	Respiratory effort

	works from distance through clothing and duvet.	works from distance through clothing.	bands (chest and abdomen) in direct contact with the subject. Nasal cannula, measures nasal pressure.
Measurement positions	Subject can be Seated or Lying down	Seated	Lying down
Parameters displayed	Respiratory Rate	Respiratory Rate	Respiratory rate and heart rate.
Technology Platform	Pulsed radar as its sensor technology.	Pulsed radar as its sensor technology.	Digital recorder connected to commercially available electrodes, cannulas, and thermistors.
RR Measurement Range	7 - 38 breaths per minute	Not available.	Not available.
Sampling rate of RR data	0.333 Hz	Not available.	Not available.
Update/Transmission Rate	0.333 Hz	Not available.	No real-time data, offline analysis only.

Summary of Non-Clinical Testing

The following tests were performed to demonstrate safety and effectiveness of The Circadia C100 System based on current industry standards:

- Cleaning: General cleaning procedure for monitor enclosure is recommended in the Instructions for Use.
- Biocompatibility: Not applicable as there is no direct/indirect patient contacting components.
- Software Verification: The software development and testing were executed with consideration to IEC 62304 Medical device software – Software life cycle processes.
- Electromagnetic Compatibility, Electrical Safety, Wireless Coexistence and Battery Safety: The subject device is tested in compliance with:
    - IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint) 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 Compatibility - Requirements And Tests
    - IEEE C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence
- Performance Testing - Bench: A number of bench testing were executed using internal test protocols to demonstrate The C100 Circadia System performance met acceptance:
    - Circadia Monitor Drop Test
    - Circadia Monitor Power Cord/Button Fatigue Test

Circadia believes that the aforementioned non-clinical testing demonstrate that the subject device is designed and manufactured in such a way that, when used under the conditions and for the purposes intended, the safety and effectiveness, as well as the performance characteristic of the subject device is substantial equivalent to the predicate device.

Summary of Clinical Testing

To evaluate the performance of the Circadia C100 System, the subject device was compared to gold standard manually scored end-tidal CO2 capnography data (device cleared in K040875 and K120888) in 12 patients. Performance of the subject device was also compared to a chest and abdomen worn band (device cleared in K122516) in 26 patients. The accuracy of Respiration rate was found to be +/- 2 breaths/min (accuracy rate 88.2%) and the 95% limits of agreements was -3.2 to +0.7 breaths/min. Thus the aforementioned clinical testing demonstrate that the overall performance of the subject device on a total of 38 subjects with a wide range of age, body- mass index, and gender, as well as various health conditions, subject postures, aspect angle, monitoring distance, presence of duvet, etc. to reflect intended user profile and conditions, for spot and continuous measurement, supports substantial equivalence to the predicate.

Conclusion

Based on the testing performed, it can be concluded that the subject device does not raise new/different questions of safety or effectiveness compared to the predicate device. The indications for use, technological characteristics, and performance characteristics for The Circadia C100 System are assessed to be substantially equivalent to the predicate device.