April 24, 2023

Casana Care, Inc.
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting
1555 King Street,
Suite 300
Alexandria, Virginia 22314

Re: K222330
Trade/Device Name: The Heart Seat
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA
Dated: March 27, 2023
Received: March 27, 2023

Dear Donna-Bea Tillman:

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 Shruti N. Mistry -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)*
K222330

Device Name
The Heart Seat

Indications for Use *(Describe)*
The Heart Seat is a replacement for a standard toilet seat that is indicated for use in a home environment. The Heart Seat is intended to be used for measuring, displaying, reviewing and storing non-invasive functional oxygen saturation of arterial hemoglobin (SpO2) and heart rate (HR) in adults of at least 22 years of age with weight ranging from 90 to 350 pounds. Data from the Heart Seat are collected whenever the seat is used and are automatically uploaded to the Casana Cloud where they can be viewed by the healthcare provider. The Heart Seat is not intended for continuous monitoring.

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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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for The Heart Seat is provided below.

1. SUBMITTER

Applicant:	Casana Care, Inc. 150 Metro Park Suite A Rochester, NY 14623
Contact:	Kara Johnson Vice President Regulatory Affairs and Quality Assurance Casana Care, Inc. 150 Metro Park Suite A Rochester, NY 14623 kjohnson@casanacare.com
Submission Correspondent:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting 1555 King St, Suite 300 Alexandria, VA 22314 410-531-6542 dtillman@biologicsconsulting.com
Date Prepared:	April 18, 2023

2. DEVICE

Device Trade Name:	The Heart Seat
Device Common Name:	Multi-Parameter Patient Monitor
Classification Name	21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class:	II
Product Code:	Primary: MWI Secondary: DQA

3. PREDICATE DEVICE

Predicate Device: K210086 Vitals360® Multi-Vitals Mobile Monitor

4. DEVICE DESCRIPTION

The Heart Seat™ is a prescription use remote monitoring system built into a toilet seat. It is intended for physiological monitoring in the home setting. The device and platform are tools intended to support clinicians by providing them with data to help them better manage patients. Monitored users (or Patients) sit on the seat for their data to be captured and sent to the cloud. Clinical users interact with the clinical cloud-based application that provides the patient measurements.

5. INTENDED USE/INDICATIONS FOR USE

The Heart Seat is a replacement for a standard toilet seat that is indicated for use in a home environment. The Heart Seat is intended to be used for measuring, displaying, reviewing and storing non-invasive functional oxygen saturation of arterial hemoglobin (SpO2) and heart rate (HR) in adults of at least 22 years of age with weight ranging from 90 to 350 pounds. Data from the Heart Seat are collected whenever the seat is used and are automatically uploaded to the Casana Cloud where they can be viewed by the healthcare provider. The Heart Seat is not intended for continuous monitoring.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The Vitals360 and the Heart Seat are both prescription-use devices intended to be used in the home environment to collect physiological data from users 18 years and older. The physiological data collected by the Heart Seat is a subset of that collected by the Vitals360. While there are differences in the form factors of the devices, they have the same intended use, which is to provide for the measurement, display, review, and storage of physiological data.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (Vitals360® Multi-Vitals Mobile Monitor, K210086).

Table 1: Technological Comparison

	Proposed Device	**Predicate Device**	**Discussion of Differences**
510(k) Number	TBD	K210086	N/A
Applicant	Casana Care, Inc.	VoCare, Inc.	N/A
Device Name	Heart Seat	Vitals360® Multi-Vitals Mobile Monitor	N/A

	Proposed Device	**Predicate Device**	**Discussion of Differences**
Classification Regulation	21 CFR 870.2300	21 CFR 870.2300	N/A
Product Code	MWI, DQA	MWI, DQA, DSH, DXN, FLL	Heart Seat provides a subset of the predicate features
Prescription/OTC	Prescription	Prescription	Same
Use environment	Home	Home, clinic	Heart Seat can be used in a subset of the predicate use environments
Intended Population	18 years and older	18 years and older	Same
Modes	Remote monitoring	Point of Care Remote monitoring	Heart Seat provides a subset of the predicate features
Parameters measured	SpO_2, HR	SpO_2, HR, NIBP, Temp, Height, Weight	Heart Seat provides a subset of the predicate features
Data upload	Automatically - WiFi	Automatically – WiFi or Cellular	Heart Seat provides a subset of the predicate features
Data storage location	Casana Cloud	Third party MDDS	Both provide options for remote storage of data
Patient Identification	Uses BioID software algorithm	None	Clinical testing demonstrates that device meets specifications, user needs and intended uses
SpO_2 Functionality			
Principle of operation	PPG	PPG	Same
Measurement site	Thigh	Fingertip	Different locations; clinical data demonstrates equivalent performance
Measurement range	70% - 100%	70% - 100%	Same

	Proposed Device	Predicate Device	Discussion of Differences
Measurement accuracy performance (Arms)	±3.5% (70-100%)	±2% (90~100%), ±4% (70~89%)	Clinical data demonstrates equivalent performance
Heart Rate			
Source	Single lead ECG	Single lead ECG (two embedded metal electrodes)	Same
Measurement site	Thigh	Fingertip	Different locations; clinical data demonstrates equivalent performance
Measurement range	40-200 bpm	30 – 240 bpm	Heart Seat provides a subset of the predicate range. Outside of the Heart Seat range, no value is reported.
Resolution	1 bpm	1 bpm	Same
Measurement accuracy	Specification: ±5bpm or ±10%, whichever is greater Actual Performance: Mean error 0.8bpm	Specification: ±2bpm or ±2%, whichever is greater	Clinical data demonstrates equivalent performance

In conclusion, the differences in technological characteristics do not raise new questions of safety and effectiveness.

7. PERFORMANCE DATA

Biocompatibility Testing

The subject device is considered surface contacting for a or a limited duration (<24 hours). A biocompatibility evaluation was performed in accordance with ISO 10993-1:2018 and FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process" and FDA's draft guidance

"Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin,". Based on the evaluation biocompatibility testing is not required.

Electrical safety and electromagnetic compatibility (EMC)

The Heart Seat was tested in accordance with:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-11: 2020 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
- ISO 80601-2-61:2017 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEEE/ANSI C63.27:2017 American National Standard For Evaluation Of Wireless Coexistence
- IEC 60086-4 Edition 5.0 2019-04 Primary batteries - Part 4: Safety of lithium batteries [Including: Corrigendum 1 (2019) and Corrigendum 2 (2020)]
- UN 38.3: Transportation Testing for Lithium Batteries and Cells

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered moderate as an erroneous diagnosis or a delay in delivery of appropriate medical care could only lead to a minor injury.

Bench Testing

The following mechanical testing was performed on the Heart Seat

- Dynamic rocker testing to test the integrity of the mounted seat assembly including the hinge, Side to Side Stability testing, Cyclical load testing, and Slow close seat endurance testing

The Heart Seat was also tested in accordance with:

- ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ANSI AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms

- IEC 60601-2-27 Edition 3.0 2011-03Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Casana conducted a Heart Rate Validation study in 117 healthy subjects comparing Heart Rate measurements reported by the Heart Seat to those obtained from a 3-lead ECG device. A total of 349 heart rate measurement pairs were collected, and 348/349 data points over the range of 40 to 103 bpm meet the Pass/Fail criteria of an Absolute Accuracy ≤ 5 bpm or 10% (whichever is greater) when compared to both the reference average and the reference median. Subgroup analyses based on subject sex and aged (the two variables that might impact the results) showed no meaningful difference in performance.

Casana conducted an SpO2 Clinical Validation study in accordance with the FDA Pulse Oximeter Guidance Document and the FDA recognized standard ISO 80601-2-61:2017 under steady state no-motion conditions. Thirteen subjects provided data for the final analysis, three of whom had Fitzpatrick VI skin tone. The study met the acceptance criteria with an A_{RMS} of 2.7 over the range of 70-100%.

Casana conducted a BioID Validation study to demonstrate that the biometric identification algorithm used by the Heart Seat is capable of identifying someone using the seat as the desired/designated user with sufficiently high accuracy without missing too many of that desired/designated user's recordings. The study enrolled 125 subjects with a range of ages, BMI, and skin tone intended to represent the intended users. The study met both primary endpoints:

- The overall mean False Match Rate (FMR) was 0.7% with an upper 95% CI of 0.89%. The FMR is the % of total number of sit recordings (true nonmatches) where the non-designated user is incorrectly IDed as the designated user.
- The overall mean FNMR (False Negative Match Rate) was 15.3% with an upper 95% CI of 20.47%. The FNMR is the % of total number of sit recordings where the designated user is incorrectly IDed as a non-designated user.

8. CONCLUSION

Based on the detailed comparison of the intended use, indications for use, and specifications for the predicate Vitals360® Multi-Vitals Mobile Monitor (K210086), the performance testing, conformance with applicable standards, clinical testing and software verification testing, the Heart Seat can be found substantially equivalent to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness.