May 11, 2018

ZOLL Manufacturing Corporation
Dawn Chang
Sr. Regulatory Affairs Manager
2000 Ringwood Avenue
San Jose, California 95131

Re: K172510
Trade/Device Name: µCor Heart Failure and Arrhythmia Management System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, DSB
Dated: April 18, 2018
Received: April 20, 2018

Dear Dawn Chang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K172510

Device Name
µCor Heart Failure and Arrhythmia Management System

Indications for Use *(Describe)*
The µCor Heart Failure and Arrhythmia Management System is intended to periodically record, store, and transmit Thoracic Fluid Index. The µCor Heart Failure and Arrhythmia Management System is also intended to continuously record and store, and periodically transmit ECG, Heart Rate, Respiration Rate, Activity and Posture. The data provided will aid medical professionals as they diagnose and identify various clinical conditions, events, and/or trends.

The µCor Heart Failure and Arrhythmia Management System is intended for use in clinical and home settings and is indicated for patients who are 21 years of age or older:

i) Who require monitoring for the detection of non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmias; or

ii) requiring fluid management.

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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5. 510(k) Summary

510(k) Owner:	**ZOLL Manufacturing Corporation** **121 Gamma Drive** **Pittsburgh, PA 15238** **USA**
Contact:	**Zachary Nelson** **Sr. Regulatory Affairs Engineer** **Phone: 412-968-3333 x14814** **Fax: 412-592-0953** **Email: znelson@zoll.com**
Date Summary Prepared:	**May 11, 2018**
Trade Name:	**µCor Heart Failure and Arrhythmia Management System**
Common Name:	**Management and Monitoring System**
Device Classification Name:	**Monitor, Physiological, Patient (with arrhythmia detection or alarms)** **Arrhythmia Detector and Alarm** **Plethysmograph, Impedance**
Product Code:	**MHX, DSI, DSB**
Classification Regulation:	**870.1025, 870.2770**
Device Classification:	**II**
Classification Panel:	**Circulatory System Devices Panel (74)**
Predicate Device:	**AVIVO Mobile Patient Management System (K113187) – Primary Predicate** **ZOE Fluid Status Monitor (K133301) – Secondary Predicate** (used for the comparison of thoracic impedance measurement only)
Reference Device:	**CoVa™ Monitoring System (K142087)**
Comparator Device:	**ZOLL X-Series (K142915)** (used in validation testing)

Device Description

The µCor Heart Failure and Arrhythmia Management System noninvasively monitors patients' clinical parameters (Thoracic Fluid Index, ECG, Heart Rate, Respiration Rate, Activity, and Posture). It acquires radiofrequency, ECG and accelerometer signals via the patient-worn device; these raw date are transmitted wirelessly to a remote Server for processing into the clinical parameters. The µCor Heart Failure and Arrhythmia Management System is for prescription use only. It is intended for use in outpatient clinic and home settings, with a monitoring period for up to 30 days.

The µCor Heart Failure and Arrhythmia Management System consists of the following components:

- Sensor – a patient worn device for signal acquisition.
- Patch – a single use, disposable adhesive piece adhered to the patient's body and allow for Sensor attachment.
- Charger – the Charger recharges the Sensor and the Gateway. The Sensor typically requires recharging after 5 days. The Gateway typically requires recharging every day.
- Gateway – An off-the-shelf item, the Gateway is essentially a cellphone that relays data and passes commands between the Sensor and the Server.
- Server – Server refers to the hardware and the processing software, and resides in a cyber-secure location. The software analyzes the raw data received from the Sensor and processes the data into clinical values for eventual presentation to the physicians via an independent monitoring center (IDTF) that is regulated under 42 CFR 410.33.

Raw data from the Sensor to the Gateway is transmitted via Bluetooth; the Gateway then transmits this data to the Server via TCP/IP over WiFi or cellular network for data processing and analysis.

Indications for Use Statement

The µCor Heart Failure and Arrhythmia Management System is intended to periodically record, store, and transmit Thoracic Fluid Index. The µCor Heart Failure and Arrhythmia Management System is also intended to continuously record and store, and periodically transmit ECG, Heart Rate, Respiration Rate, Activity and Posture. The data provided will aid medical professionals as they diagnose and identify various clinical conditions, events, and/or trends.

The µCor Heart Failure and Arrhythmia Management System is intended for use in clinic and home settings and is indicated for patients who are 21 years of age or older:

i) Who require monitoring for the detection of non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmias; or

ii) Requiring fluid management.

Technological Characteristics and Substantial Equivalence Discussion

The µCor Heart Failure and Arrhythmia Management System's technological characteristics are substantially equivalent to those of its predicate devices. All of the devices are non-invasive, prescription use, and indicated for home setting. Same as both predicates, the µCor Heart Failure and Arrhythmia Management System is intended for the monitoring of patient's physiological data, and indicated for patients with fluid management problems. Both the µCor Heart Failure and Arrhythmia Management System and the AVIVO (primary predicate device) use a body-worn sensor to acquire the physiological data of interest, with the Gateway to relay the physiological data, and a remote server to process the data. Both the µCor Heart Failure and Arrhythmia Management System and the AVIVO use a single-lead ECG recorder to obtain ECG signal and to derive Heart Rate. Both the µCor Heart Failure and Arrhythmia Management System and the AVIVO derive data collected by a tri-axis accelerometer to derive activity and posture. The µCor Heart Failure and Arrhythmia Management System Respiration Rate is derived from data collected by the tri-axis accelerometer while the AVIVO Respiration Rate is derived from impedance. Both the µCor Heart Failure and Arrhythmia Management System and the AVIVO monitor thoracic fluid based on thoracic impedance measurements. The µCor Heart Failure and Arrhythmia Management System obtains its impedance measurement, i.e. Thoracic Fluid Index, from radiofrequency signal while the AVIVO and the ZOE obtain their impedance measurements using electrical current. The AVIVO's output is called Body Fluid Status and is provided in ohms, while the ZOE's output is Thoracic Impedance (aka Thoracic Z_o), also provided in ohms. The minor differences in technology between the µCor Heart Failure and Arrhythmia Management System and the predicate devices used to measure thoracic fluid index/thoracic impedance and respiration rate do not raise new type of safety and effectiveness questions. These differences have been assessed in bench, preclinical, and clinical testing. Results established that the µCor Heart Failure and Arrhythmia Management System performs as intended and is substantially equivalent to its predicate devices. **Table 1** provides a comparison chart between the subject and predicate devices.

Table 1: Comparison Chart between µCor Heart Failure and Arrhythmia Management System, AVIVO and ZOE

	µCor Heart Failure and Arrhythmia Management System (Subject Device)	**AVIVO (Primary Predicate)**	**ZOE (Secondary Predicate)**	**Comparison**
Intended Use	Ambulatory recording and monitoring of physiological parameters	Ambulatory recording and monitoring of physiological parameters	Recording and monitoring of physiological parameters in home and clinical settings	Same
Intended Use Environment	Home, clinic	Home, clinic	Home, clinic	Same
Parameters Monitored	Thoracic Fluid Index	Body Fluid Status	Thoracic Impedance (Thoracic Z_o)	Similar The µCor Heart Failure and Arrhythmia Management System Thoracic Fluid Index is obtained by comparing the patient's current Thoracic Impedance (T2) to his/her baseline (T1) and is presented in index format (T2/T1), e.g. 1.5. AVIVO Body Fluid Status and the ZOE Thoracic Z_o are both presented in ohms and are not relative to the patient's baseline. The µCor Heart Failure and Arrhythmia Management System, the AVIVO and the ZOE monitor patient's thoracic fluid by trending the Thoracic Impedance measurements taken periodically. The µCor Heart Failure and Arrhythmia Management System

	µCor Heart Failure and Arrhythmia Management System (Subject Device)	AVIVO (Primary Predicate)	ZOE (Secondary Predicate)	Comparison
				and the AVIVO are substantially equivalent.
	ECG	ECG	NA	Same
	Heart Rate	Heart Rate (including HR variability)	NA	Same. Both µCor Heart Failure and Arrhythmia Management System and AVIVO measure Heart Rate.
	Respiration Rate	Respiration Rate (including RR variability)	NA	Same. Both µCor Heart Failure and Arrhythmia Management System and AVIVO measure Respiration Rate.
	Activity	Activity	NA	Same.
	Posture	Posture	NA	Same.
System Components	- Sensor - Patch - Charger - Gateway - Server	- PiiX (aka Adherent Device) - zLink (aka Gateway) - Server	NA	Same. The µCor Heart Failure and Arrhythmia Management System and AVIVO both have the following components serving the same purpose: (1) a body-worn sensor to acquire the physiological data of interest; (2) Gateway to relay the physiological data; (3) a remote server to process data.
Arrhythmia Detection	Detect non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrythmias.	Detect non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy,	NA	Similar. Testing of the µCor Heart Failure and Arrhythmia Management System did not include testing of paroxysmal SVT or conduction disorders.

	µCor Heart Failure and Arrhythmia Management System (Subject Device)	AVIVO (Primary Predicate)	ZOE (Secondary Predicate)	Comparison
		bradyarrhythmias and conductions disorders		
Date Transmission	- Sensor to Gateway: Bluetooth - Gateway to Server: WiFi or Cellular	- PiiX to Gateway: Bluetooth - Gateway to Server: Cellular	NA	Both µCor Heart Failure and Arrhythmia Management System and AVIVO transmit data using Bluetooth technology and a cellular network. The µCor Heart Failure and Arrhythmia Management System additionally uses WiFi, a standard networking technology covered under IEEE 802.11. The Gateway of the µCor Heart Failure and Arrhythmia Management System is essentially an off-the-shelf standard cellphone approved by FCC and PTCRB and is certified to work in the cellular network licensed frequencies and designed to co-exist with other users of the cellular frequency band, ensuring data transmission. Additionally, co-existence testing has been conducted on the µCor HFAMS. Therefore, the µCor Heart Failure and Arrhythmia

	µCor Heart Failure and Arrhythmia Management System (Subject Device)	AVIVO (Primary Predicate)	ZOE (Secondary Predicate)	Comparison
				Management System is at least as safe and effective as the AVIVO.

Performance Data

The µCor Heart Failure and Arrhythmia Management System was evaluated in non-clinical, preclinical, and clinical testing, which are summarized in **Table 2** below.

Table 2: µCor Heart Failure and Arrhythmia Management System V&V Activities Summary

<table>
<tr><th>Title</th><th>Description</th></tr>
<tr><td>MaTcH Clinical Study</td><td>This is a prospective, non-significant risk, randomized, 2-arm study, premarket validation study. A non-inferiority design was used to test substantial equivalence between the µCor 3.0 (which uses identical RF technology to monitor thoracic impedance) and the ZOE in the ability to measure thoracic impedance. This was done by comparing the correlation between µCor 3.0 measurements and ultrafiltration volume (UFV) with the correlation between ZOE measurements and UFV.
In this study, 20 hemodialysis patients were enrolled wearing the µCor 3.0. All patients had the predicate device ZOE applied in the sternum location. During the patient's dialysis session, readings from both the µCor 3.0 and the ZOE, as well as the ultra-filtration volume extracted were recorded simultaneously. The results are summarized below:

<table>
<tr><th>µCor 3.0 Mean Correlation</th><th>ZOE Mean Correlation</th><th>µCor 3.0 95% CI</th></tr>
<tr><td>0.95</td><td>0.211</td><td>[0.92, 0.99]</td></tr>
</table>

The reference device (CoVa) also measures thoracic impedance in an ambulatory setting. The CoVa device has a mean correlation of r=0.93 with UFV. To test for substantial equivalence, a non-inferiority design was used. Using a non-inferiority margin, δ, or -0.05, the lower confidence interval for the µCor 3.0 is greater than the pre-specified acceptance criteria of 0.093-0.05 = 0.88. Therefore the alternate hypothesis that the µCor 3.0 was non-inferior to CoVa was accepted.

The study demonstrates that the µCor 3.0 (and by extension the µCor Heart Failure and Arrhythmia Management System) is substantially equivalent to the ZOE (secondary predicate) and CoVa (reference).</td></tr>
</table>

<table>
<tr><td>ViVUS Clinical Study</td><td>This is a prospective, non-significant risk, non-randomized, premarket study to validate the capability of the µCor 3.0 (which uses identical accelerometers, ECG acquisition circuitry, and algorithms as the µCor Heart Failure and Arrhythmia Management System) to monitor ECG, Heart Rate, Respiration Rate, Posture and Activity.

In this study, 15 healthy human volunteer subjects wore the µCor 3.0. Each subject was asked to perform the following activities during the study: breathing, walking and resting. Respiration rates, ECG, Heart Rates, Activity and Postures were collected during these activities. For comparison, the ZOLL X-Series (an FDA cleared device under K142915) was used as the comparator device for Respiration Rate, ECG and Heart Rate. Results are summarized below:
<table>
<tr><th>Parameter</th><th>Mean Difference</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>RR (metronome-guided)</td><td>0.188</td><td>± 2.2 breaths per minute</td><td>Pass</td></tr>
<tr><td>RR (spontaneous)</td><td>-0.481</td><td>± 2.2 breaths per minute</td><td>Pass</td></tr>
<tr><td>HR</td><td>-0.474</td><td>± 3.16 bpm</td><td>Pass</td></tr>
<tr><td>Activity</td><td>0.9908</td><td>> 0.9 (kappa coefficient)</td><td>Pass</td></tr>
<tr><td>Posture</td><td>0.9908</td><td>> 0.9 (kappa coefficient)</td><td>Pass</td></tr>
</table>

The results show the ability of the µCor 3.0 (and by extension the µCor Heart Failure and Arrhythmia Management System) to collect ECG data, measure Heart Rate and Respiration Rate, and classify Posture and Activity, within the accuracy defined in the endpoints.</td></tr>
<tr><td>Animal Safety Study</td><td>This GLP study was conducted to assess adverse effects resulting from the µCor 3.0 (which uses the same Patch and RF technology) following application on the chest wall and activation in the porcine model. Results of the study demonstrate that the µCor 3.0 (and by extension the µCor Heart Failure and Arrhythmia Management System) is safe through macroscopic and microscopic evaluations of the major visceral organs tissues subjacent to the test devices with a RF measurement paradigm equivalent to an average of 42 days.</td></tr>
<tr><td>Mechanical Force</td><td>This bench testing was conducted to validate the ability of the µCor Heart Failure and Arrhythmia Management System Sensor and Patch snap-in mechanism to resist mechanical force anticipated under normal use throughout its expected lifetime. In this testing, the Sensors and Patches went through cycles of insertion and removal. Results showed that there was no degradation in the electrical connection in the Patch wires or in the spring-loaded latch in the Sensor.</td></tr>
</table>

<table>
<tr><td>Respiration Rate Measurement Accuracy</td><td>This bench testing was conducted to verify the accuracy of the µCor Heart Failure and Arrhythmia Management System respiration rate estimation. In this testing, the µCor Heart Failure and Arrhythmia Management System Sensor was attached to a mechanical fixture which simulated the respiration movement; accelerometer readings were acquired by the Sensor, and then fed to the algorithm for respiration rate estimation. Results are summarized below:
<table>
<tr><th></th><th>µCor Heart Failure and Arrhythmia Management System - reference</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>Standard Deviation</td><td>0.12</td><td>< 1</td><td>Pass</td></tr>
<tr><td>Max</td><td>0.294</td><td>< 2</td><td>Pass</td></tr>
</table></td></tr>
<tr><td>Impedance Measurement Accuracy</td><td>This bench testing was conducted to demonstrate the impedance measurement accuracy of the µCor Heart Failure and Arrhythmia Management System by comparing its ability to detect impedance change against that of a Virtual Network Analyzer (VNA). Results show that the worst case deviation between the µCor Heart Failure and Arrhythmia Management System and the VNA measurement is 0.4%, while the average deviation between the µCor Heart Failure and Arrhythmia Management System and the VNA measurement is 0.02%, meeting the acceptance criteria of ≤ 0.5%.</td></tr>
<tr><td>Arrhythmia Detection Algorithm</td><td>The µCor Heart Failure and Arrhythmia Management System ECG analysis software performance was verified by testing to AAMI/ANSI EC 57:2012. Test methodology included applying the algorithm under test to the ECG databases required by the standard. The test algorithm was required to generate an attribute file with the analysis results. Test results were compared to reference results, which were available as part of the database, using comparison applications provided by PhysioNet. Results demonstrate that the performance of the µCor Heart Failure and Arrhythmia Management System ECG analysis software meets the clinical requirements for arrhythmia detection and heart rate estimation.</td></tr>
<tr><td>Basic Safety and Essential Performance for Medical Electrical Equipment</td><td>• AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
• IEC 60601-1-11 Ed 2.0 2015-01
• AAMI/ANSI/IEC 60601-2-47:2012
Results demonstrate that µCor Heart Failure and Arrhythmia Management System meet the safety and performance requirements set forth in the standards.</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>• AAMI/ANSI/IEC 60601-1-2: 2014</td></tr>
</table>

	Results demonstrate that µCor Heart Failure and Arrhythmia Management System meet the emissions and immunity requirements set forth in the standard.
Co-existence	Co-existence testing was conducted to validate the data channel telemetry of µCor Heart Failure and Arrhythmia Management System by demonstrating the performance of the system's data transmission link is not affected by the signals from other RF wireless technologies typically found in a home setting. Results demonstrate that the µCor Heart Failure and Arrhythmia Management System transmits measured data without interruption, loss or corruption of data in the presence of other representative RF wireless devices.
Biocompatibility (cytotoxicity, irritation, sensitization)	• AAMI/ANSI/ISO 10993-5:2009/(R)2012 Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity • ISO 10993-10 3rd Ed (2010) Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization Results demonstrate that the System Patch meets the biocompatibility requirements set forth in the standards.
Shelf-life Testing	Accelerated aging test was conducted with the System Patch. Data collected to date supports the claimed shelf life.
Shipping & Packaging Testing	Shipping tests were conducted on µCor Heart Failure and Arrhythmia Management System packaging. The testing followed ASTM D4169-16. Results demonstrated that the function of µCor Heart Failure and Arrhythmia Management System is not adversely affected during transportation.
Software	Following FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued on May 11, 2005, The following items are included in the 510(k): • µCor Heart Failure and System Level of Concern • Software Description • Device Hazard Analysis • Software Requirements Specification (SRS) • Architecture Design Chart • Software Design Specification (SDS) • Traceability Analysis • Software Development Environment Description • Verification and Validation Documentation • Revision Level History • Unresolved Anomalies

Conclusion

The µCor Heart Failure and Arrhythmia Management System has the same intended use and similar technological characteristics as the predicate devices. Any minor differences in the µCor Heart Failure and Arrhythmia Management System as compared to the predicate devices do not raise any new questions of safety or effectiveness. As summarized in the Performance Data section above, non-clinical and clinical tests demonstrate that the µCor Heart Failure and Arrhythmia Management System performs similarly to the legally marketed predicate devices. Test results confirm that the µCor Heart Failure and Arrhythmia Management System is as least as safe and effective as the predicate devices; therefore, the µCor Heart Failure and Arrhythmia Management System is substantially equivalent to its predicate devices.