December 19, 2019

ZOLL Manufacturing Corporation
℅ Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group
5737 Kentucky Avenue #3
Pittsburgh, Pennsylvania 15232

Re: K190939
Trade/Device Name: ZOLL 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
Dated: November 22, 2019
Received: November 25, 2019

Dear Michael Nilo:

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 Jessica Paulsen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190939

Device Name
ZOLL Arrhythmia Management System

Indications for Use *(Describe)*

The ZOLL Arrhythmia Management System (AMS) is intended to continuously record, store, and 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.

AMS is intended for use in clinic and home settings. AMS is indicated for patients who are 21 years of age or older 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.

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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510(k) Summary

510(k) Owner:	**ZOLL Manufacturing Corporation** **121 Gamma Drive** **Pittsburgh, PA 51238** **U. S. A.**
Contact:	**Zachary Nelson** **Sr. Regulatory Affairs Engineer - Premarket** **Phone: 412-968-3333 x14814** **Fax: 412-567-9574** **Email: znelson@zoll.com**
Date Summary Prepared:	**December 17, 2019**
Trade Name:	**ZOLL Arrhythmia Management System**
Common Name:	**Management and Monitoring System**
Device Classification Name:	**Monitor, Physiological, Patient (with arrhythmia detection or alarms)** **Arrhythmia Detector and Alarm**
Product Code:	**MHX, DSI**
Classification Regulation:	**870.1025**
Device Classification:	**II**
Classification Panel:	**Circulatory System Devices Panel (74)**
Predicate Device:	**K172510 - µCor Heart Failure and Arrhythmia Management System, ZOLL Manufacturing Corporation**
Reference Device:	**K133701 - NUVANT MCT System, Corventis, Inc.**
Comparator Devices:	**K102507 – Aera CT, TZ Medical, Inc** (used for validation) **K972795 – Cardio-Card Management System II, Nasiff Associates, Inc.** (used for validation)

Device Description

The **ZOLL Arrhythmia Management System (AMS)** noninvasively monitors patients' clinical parameters (ECG, Heart Rate, Respiration Rate, Activity, and Posture). These raw data are transmitted wirelessly to a remote Server for processing into the clinical parameters. The ZOLL Arrhythmia Management System is for prescription use only. It is intended for use in outpatient clinic and home settings.

The ZOLL 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.

The ZOLL Arrhythmia Management System Patch and Sensor will be placed on the upper left chest ("front" location).

Indications for Use Statement

The ZOLL Arrhythmia Management System (AMS) is intended to continuously record, store, and 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.

AMS is intended for use in clinic and home settings. The AMS is indicated for patients who are 21 years of age or older 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.

Technological Characteristics and Substantial Equivalence Discussion

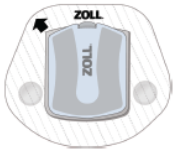
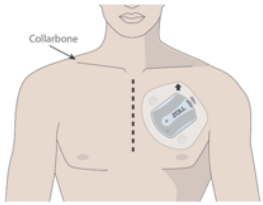
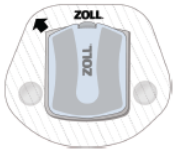
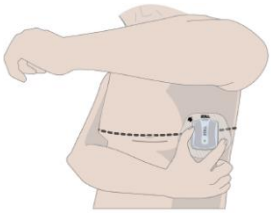
The AMS technological characteristics are substantially equivalent to K172510 - µCor Heart Failure and Arrhythmia Management System. The devices are non-invasive, prescription use, and indicated for home setting. Both devices have similar intended uses and are identical in form and function. The ZOLL Arrhythmia Management System represents an

iterative change from the predicate ZOLL device. The new device also uses 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. The proposed device prescribes placement on the upper left chest to monitor heart activity only; whereas the predicate device uses a side location to monitor heart activity and thoracic fluid index (TFI).
The removal of TFI monitoring and the difference in device placement between the ZOLL Arrhythmia Management System and the µCor Heart Failure and Arrhythmia Management System does not raise new types of safety and effectiveness questions. These differences have been assessed in bench and clinical testing. Results established that the AMS performs as intended and is substantially equivalent to its predicate device. **Table 1** provides a comparison chart between the subject and predicate devices.

Table 1: Comparison Chart between Arrhythmia Management System with (AMS) and µCor Heart Failure and Arrhythmia Management System (HFMAS)

	AMS (Proposed Device)	**HFAMS K172510 (Predicate Device)**	**Comparison Comments**
Intended Use	Ambulatory recording and monitoring of physiological parameters	Ambulatory recording and monitoring of physiological parameters	Same
Indications for Use (IFU)	The ZOLL Arrhythmia Management System (AMS) is intended to continuously record, store, and 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 ZOLL Arrhythmia Management System is indicated for patients who are 21 years of age or older	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	Indications for use have been updated to remove monitoring of Thoracic Fluid Index. Cleared reference devices also do not monitor Thoracic Fluid Index.

	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.	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) require fluid management.	
Intended Use Environment	Home, clinic	Home, clinic	Same.
Parameters Monitored	ECG	ECG	Same.
	Heart Rate	Heart Rate	
	Respiration Rate	Respiration Rate	
	Activity	Activity	
	Posture	Posture	
	n/a	Thoracic Fluid	The proposed device has the capability to monitor Thoracic Fluid; however, the API has been updated to disable access to this data.
System Configuration & Components Characteristics			
Components	- Sensor - Patch - Charger - Gateway - Server	- Sensor - Patch - Charger - Gateway - Server	Same.
Product Configuration	The Sensor acquires the physiological data of interest. Data is transmitted to the Gateway embedded within the Charger, which is then	The Sensor acquires the physiological data of interest. Data is transmitted to the Gateway embedded within the Charger, which is then forwarded to the Server for derivation.	Same.

	forwarded to the Server for derivation.		
Body Worn Component Form Factor and Wear Location	The Sensor is attached to the (adhesive) Patch, which enables the patient worn effect.  The device is placed on the upper left chest, just below the collarbone. 	The Sensor is attached to the (adhesive) Patch, which enables the patient worn effect.  The device is placed on the "side" location: below the left armpit with the nipple aligned anywhere between the top and middle of the Sensor. 	Similar. The body worn component is identical. ZOLL is proposing placement in the upper chest location. Corventis reference device is also worn in the upper chest with the same configuration.
Disposable Patch or Electrodes Wear Duration	5 days for each Patch.	5 days for each Patch.	Same.
Data Transmission Technology	- Sensor to Gateway: Bluetooth - Gateway to Server: WiFi or Cellular	- Sensor to Gateway: Bluetooth - Gateway to Server: WiFi or Cellular	Same.
Clinical Parameters			
Clinical Parameters Monitored	- ECG (script) - Heart Rate (beats per minute) - Respiration Rate (breaths per minute)	- Thoracic Fluid Index - ECG (script) - Heart Rate (beats per minute) - Respiration Rate (breaths per minute)	Similar. Thoracic Fluid Index is no longer included.

	- Activity ('active' vs. 'rest') - Posture ('supine', 'recline', or 'upright')	- Activity ('active' vs. 'rest') - Posture ('supine', 'recline', or 'upright')	
Arrhythmia detection	Detect non-lethal cardiac arrhythmias[1], such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy and bradyarrhythmias.	Detect non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy and bradyarrhythmias.	

Performance Data

The ZOLL Arrhythmia Management System was evaluated through non-clinical and clinical testing, as well as leveraged applicable data from the predicate device, as summarized below.

Non-Clinical Testing

- The ZOLL Arrhythmia Management System detection algorithm was tested to ANSI/AAMI EC57:2012. The test results met the algorithm performance requirements and can be found in the Clinical Manual.
- Software validation testing of the API and Analysis Software. The testing successfully validated the device software.

Non-Clinical Testing leveraged from the predicate device

The testing below was leveraged directly from the predicate device, as the ZOLL Arrhythmia Management System uses identical hardware and much of the same software as the predicate device.

- Mechanical bench testing of the Sensor and Patch
- Respiration Rate accuracy bench testing
- Safety testing to:
  - 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
- Electromagnetic Compatibility testing to AAMI/ANSI/IEC 60601-1-2:2014
- Wireless co-existence testing

[1] AMS detects arrhythmias and 2nd and 3rd degree AV nodal conduction disorders. This single lead ECG device should not be considered a substitute for a 12-lead ECG for assessing ECG intervals (ex. intraventricular conduction delays, QT intervals).

- Biocompatibility testing
- Shelf-Life Testing
- Shipping and Packaging Testing
- Software Testing

Clinical Testing

- Equivalency of Electrocardiograms (ECGs) Recorded by the ZOLL Arrhythmia Management System to that of a Standard Lead II ECG System
  This prospective, non-significant risk, premarket study demonstrated the ability of the ZOLL Arrhythmia Management System to capture ECGs as compared to a standard lead-II device. During the study 43 volunteers (22 females, 21 males) wore the AMS and a lead-II device simultaneously in sitting, supine, and standing positions. There were no adverse effects of complications during the study. The study demonstrated that the AMS was equivalent in capturing the below aspects of the ECG waveform, as compared to the standard lead II device:
  - P waves
  - QRS complexes
  - PR duration
  - QRS duration
  - RR interval

  The median amplitude of the AMS QRS complex was greater than or equal to the median amplitude of the standard lead-II of a 12-lead ECG comparator device.

Clinical Testing leveraged from the predicate device

- Vital Signs Validation Study of the µCor System (ViVUS)
  This prospective, non-significant risk, premarket study validated the capability of the device to monitor ECG, Heart Rate, Respiration Rate, Posture, and Activity. During the study, 15 healthy volunteers (9 females, 6 males) wore the device and were asked to perform the following activities: breathing, walking, and resting. Respiration Rate, ECG, Heart Rate, Activity, and Posture were collected during these activities. There were no adverse effects or complications during the study. The results demonstrated the ability of the device to collect ECG data, measure Heart Rate and Respiration Rate, and classify Posture and Activity.

  The results from this study apply to the ZOLL Arrhythmia Management System, as the Arrhythmia Management System utilizes the same accelerometer and ECG acquisition circuitry as the predicate device.

Conclusion

The ZOLL Arrhythmia Management System is substantially equivalent to the µCor Heart Failure and Arrhythmia Management System (K172510). Both devices are both intended to

continuously record and store, and periodically transmit ECG, Heart Rate, Respiration Rate, Activity and Posture, as well as monitor and detect non-lethal cardiac arrhythmias. Both devices are identical in form. The ZOLL Arrhythmia Management System has removed the ability to analyze Thoracic Fluid Index in order to allow for placement of the device on the upper chest, which allows for appropriate detection of non-lethal arrhythmias.