September 10, 2021

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

Re: K210160
Trade/Device Name: AlertWatch:AC
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: August 11, 2021
Received: August 12, 2021

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
External Heart Rhythm and Rate Team
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)*
K210160

Device Name
AlertWatch:AC

Indications for Use *(Describe)*
AlertWatch:AC is intended for use by physicians for secondary monitoring of ICU patients. AlertWatch:AC is also intended for use by physicians providing supplemental remote support to bedside care teams in the management and care of ICU patients. AlertWatch:AC is not intended for use in monitoring pediatric or neonatal patients.
AlertWatch:AC is a software system that combines data from the electronic medical record, networked physiologic monitors, and ancillary systems, and displays them on a dashboard view of the unit and patient. The clinical decision support is generated to aid in understanding the patient's current condition and changes over time. Once alerted by AlertWatch:AC, the physician must refer to the primary monitor, device, or data source before making a clinical decision.

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 AlertWatch:AC is provided below.

1. SUBMITTER

Applicant:	AlertWatch, Inc. 330 East Liberty St. Fourth Floor Ann Arbor, MI 48104
Contact:	Justin Adams AlertWatch, Inc. CEO Phone: 734-998-8344 Justin.adams@alertwatch.com
Submission Correspondent:	Donna-Bea Tillman, Ph. D Senior Consultant Biologics Consulting Group, Inc. 1555 King Street, Suite 300 Alexandria, VA 22314 (410) 531-6542 dtillman@biologicsconsulting.com
Date Prepared:	September 10, 2021

2. DEVICE

Device Trade Name:	AlertWatch:AC
Device Common Name:	System, Network and Communication, Physiological Monitors
Classification Name	21 CFR 870.2300 - Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class:	II
Product Code:	MSX

3. PREDICATE DEVICE

Predicate Device:	K171322 - Philips eCareManager 4.1
Reference Device:	K153335 - AlertWatch:OR

4. DEVICE DESCRIPTION

AlertWatch:AC is a secondary monitoring system used by physicians to monitor adult patients in an ICU environment. The purpose of the device is to synthesize a wide range of patient data and inform physicians of potential problems. Once alerted, the physician is instructed to refer to the primary monitoring device or EMR before making a clinical decision.

The software design includes a default set of rules and alerts that can be configured by the hospital during the installation process. AlertWatch:AC is intended to supplement, not replace, a hospital's primary EMR.

The device retrieves data from the electronic medical record (EMR) system and networked physiologic monitors, integrates this data, and performs a series of calculations to assess potential clinical issues. The information is conveyed both via organ colors and messages in the alert panel. Any alert can also be configured to send pages to physicians assigned to the patient.

5. INTENDED USE/INDICATIONS FOR USE

AlertWatch:AC is intended for use by physicians for secondary monitoring of ICU patients. AlertWatch:AC is also intended for use by physicians providing supplemental remote support to bedside care teams in the management and care of ICU patients. AlertWatch:AC is not intended for use in monitoring pediatric or neonatal patients.

AlertWatch:AC is a software system that combines data from the electronic medical record, networked physiologic monitors, and ancillary systems, and displays them on a dashboard view of the unit and patient. The clinical decision support is generated to aid in understanding the patient's current condition and changes over time. Once alerted by AlertWatch:AC, the physician must refer to the primary monitor, device, or data source before making a clinical decision.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Both the subject AlertWatch:AC and the predicate eCareManager device are used by physicians in a hospital environment to monitor patients. Both devices are only intended for secondary monitoring and users must refer to the primary monitor or primary clinician before making clinical decisions. Both systems aggregate and summarize information to help users make informed decisions. Therefore, the differences in indications for use do not constitute a new intended use, and eCareManager can be used as a primary predicate for the subject AlertWatch:AC.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (Philips eCareManager 4.1, K171322).

Table 1: Technological Comparison

	Predicate Device	**Proposed Device**
Device Name	eCareManager 4.1	AlertWatch:AC v1.00
510(k) number	K171322	K210160
Classification	MSX	Identical
Regulation	870.2300	Identical
Intended Use environment	In-Hospital Patients	ICU
Intended Users	Trained Medical Staff	Physicians
Intended for primary monitoring?	No - only for secondary monitoring. User must refer to primary monitor or bedside clinician to confirm all decisions.	Identical
Data server	Electronic medical record, patient monitoring systems and ancillary systems connected through networks	Identical
Supported EMR systems	Epic	All current versions of Epic (2015+) and Centricity 7.63.299 The reference device (AlertWatch:OR) also supports current versions of Epic (2015+) and Centricity 7.63.299
Supported physiologic monitors	Philips	**GE Solar 9500,** **GE Carespan B850,** **Capsule Medical Device Integration System**
Organs Monitored	Heart, Lungs, Kidneys, Brain, Liver	Identical
Supported EMR Data Elements	Demographic, Diagnosis, Labs, Risk Factors & Comorbidities, Lines, Tubes and Drains, Medications, Infusions, Notes, **Images.**	Demographic, Diagnosis, Labs, Risk Factors & Comorbidities, Lines, Tubes and Drains, Medications, Infusions, Notes.
Patient Risk Scores & Acuity Calculations	Proprietary Philips Acuity Score, APACHE	SOFA and SIRS, established patient risk and acuity calculations.
Hardware platforms supported	PC	PC, **iPad, iPhone** The hardware platforms of AlertWatch:OR, the reference device, also includes the use of iOS mobile devices.

	Predicate Device	Proposed Device
Generates clinical advisories	eCareManager uses the above data to generate clinical decision support notifications that aid in understanding the patient's current condition and changes over time.	Identical
Re-display of vital sign data from primary monitors	Yes	Identical
Intended to replace primary monitors	No	Identical
Paging	Unknown	Yes. For physicians to page each other and for AlertWatch:AC to transmit alerts to the bedside providers using the hospital-established paging system.
Views	Single Patient Organ Specific Census	Single Patient Organ Specific Census
Camera	Camera hardware and software for in room video.	None. A camera is not a required element for the device to perform as intended.

There are slight differences in technological characteristics that reflect the different clinical needs of the user populations, but the general approach of retrieving data from the EMR system, integrating this data, and performing a series of calculations to assess potential patient clinical issues is the same. The differences in technological characteristics do not raise different questions of safety and effectiveness.

7. PERFORMANCE DATA

Biocompatibility Testing

There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The subject device is a software-only device. It contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

However, because AlertWatch:AC includes wireless communication, the system was evaluated in accordance with the FDA guidance document: Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (August 14, 2013). Wireless Co-existence testing was performed to establish that the wireless components work effectively in the hospital environment.

Software Verification and Validation Testing

Software verification and validation testing was 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." Verification of AlertWatch:AC was conducted to ensure that the product works as designed, and was tested with both constructed data and data from the EMR. Validation was conducted to check the design and performance of the product.

Bench Testing

- **Human Factors Study:** To better understand any potential usability issues that could interfere with the intended use of the product, AlertWatch performed a comprehensive human factors study. AlertWatch recruited 18 users and conducted a summative usability study. The results of the study showed that users with no training were able to successfully perform critical tasks and were able to use the device for its intended purpose- to clarify clinical information and support information access. AlertWatch also recruited 15 users to participate in a summative usability study on the verbal alarm signals. The results of the study showed that users with no training were able to successfully perform critical tasks and were able to use the device for its intended purpose.
- **Default Limits and Thresholds**: AlertWatch, Inc. used a two-phased approach to ensure that the default limits were clinically valid:
    1. **Review of References.** AlertWatch sought out definitive published studies that highlighted appropriate limits for certain patient conditions. This includes limits and thresholds for the green/yellow/red organ schema, as well as the alerts and formulae.
    2. **Expert Committee.** For all limits and thresholds, AlertWatch sought out the opinion and confirmation of acute care physicians at the University of Michigan Health System. Each of these clinicians reviewed the limits, provided feedback, and reviewed the final results.
- **IEC 60601-1-8:** A summary of how AlertWatch:AC addresses the primary issues identified in IEC 60601-1-8 is provided in the submission.

Animal Testing

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

Clinical Data

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

8. CONCLUSION

The subject AlertWatch:AC and the predicate Philips eCareManager 4.1 (K171322) have the same intended use, namely to provide secondary monitoring of in-hospital patients. The general approach of retrieving data from the EMR system, integrating this data, and performing a series of calculations to assess potential patient clinical issues is the same. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the results of performance testing demonstrate that the subject device performs in accordance with specifications and meets user needs and intended uses. Therefore, AlertWatch:AC has been demonstrated to be substantially equivalent to the predicate Philips eCareManager 4.1.