April 23, 2018

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

Re: K173715
Trade/Device Name: AlertWatch:OB
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: March 21, 2018
Received: March 22, 2018

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. 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

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)*
K173715

Device Name
AlertWatch:OB

Indications for Use *(Describe)*
AlertWatch:OB is intended for use by clinicians for secondary monitoring of maternal patients in the labor and delivery unit. AlertWatch:OB is a maternal surveillance system that combines data from validated electronic medical record systems, and displays them in one place. Once alerted by AlertWatch:OB, the clinician 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for AlertWatch:OB is provided below.

1. SUBMITTER

Applicant:	AlertWatch, Inc 330 East Liberty St. Fourth Floor Ann Arbor, MI 48104 Tel: Fax:
Contact:	Justin Adams CEO Phone: 734-998-8344 E-mail: Justin.adams@alertwatch.com
Submission Correspondent:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consultant Group, Inc. Phone: 410-531-6542 E-mail: dtillman@biologicsconsulting.com
Date Prepared:	December 1, 2017

2. DEVICE

Device Trade Name:	AlertWatch:OB
Device Common Name:	Physiological Patient Monitor without arrhythmia detection or alarms
Classification Name	21 CFR 870.2300 - Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class:	II
Product Code:	MWI

3. PREDICATE DEVICE

Predicate Device: AlertWatch:OR (K153335)

4. DEVICE DESCRIPTION

AlertWatch:OB is a secondary monitoring system used by OB nurses, obstetricians, and OB anesthesiologists to monitor women in the Labor and Delivery (L&D) unit. The purpose of the program is to synthesize a wide range of maternal patient data and inform clinicians of potential problems. Once alerted, the clinician is instructed to refer to the primary monitoring device or EMR before making a clinical decision.

AlertWatch:OB should only be connected to EMR systems that have been validated for use with AlertWatch:OB. AlertWatch, LLC performs the validation for each installation site.

5. INTENDED USE/INDICATIONS FOR USE

AlertWatch:OB is intended for use by clinicians for secondary monitoring of maternal patients in the labor and delivery unit. AlertWatch:OB is a maternal surveillance system that combines data from validated electronic medical record systems, and displays them in one place. Once alerted by AlertWatch:OB, the clinician must refer to the primary monitor, device, or data source before making a clinical decision.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

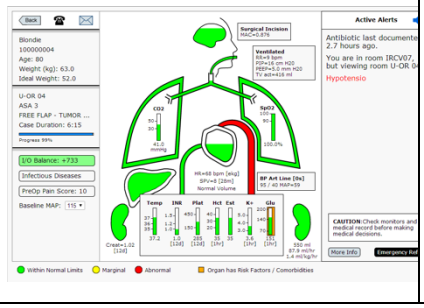
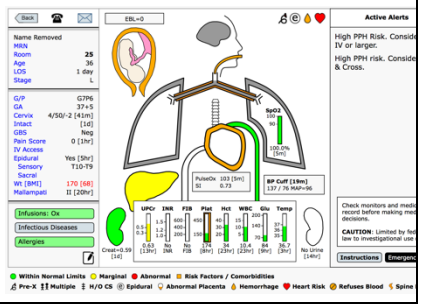
Both the subject AlertWatch:OB and the predicate AlertWatch:OR are intended for secondary monitoring of patients in the hospital. With both devices, the user is directed to refer to the primary monitor or device before making a clinical decision. The data collected, the analysis and display technology, and the alerting and paging process for both products is essentially the same. Therefore, this difference in indications for use does not constitute a new intended use, and AlertWatch:OR can be used as a primary predicate for the subject AlertWatch:OB.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (AlertWatch:OR, K153335).

Table 1: Technological Comparison

	Predicate Device	**Proposed Device**
510(k) Number	K153335	-
Applicant	AlertWatch, Inc.	AlertWatch, Inc.
Device Name	AlertWatch:OR	AlertWatch:OB
Classification Regulation	21 CFR 870.2300 - Cardiac monitor (including cardiotachometer and rate alarm)	21 CFR 870.2300 - Cardiac monitor (including cardiotachometer and rate alarm)
Product Code	MWI	MWI

	Predicate Device	Proposed Device
Intended Use environment	OR	Labor and Delivery Unit
Intended Users	Anesthesiologist, Resident, CRNA	OB Anesthesiologist, OB Physician, OB Nurse, Resident
Intended for primary monitoring?	No - only for secondary monitoring	Identical
Data server	AlertWatch:OR accesses data from the AIMS database server.	AlertWatch:OB accesses data from the EMR system.
Supported AIMS / EMR systems	Centricity, version 7.6.3 Picis / Optum, version 421 iMDsoft / Metavision, version 5.46.44	Epic 2015 UI 2
Supported physiologic monitors	GE Solar 9500 GE Carespan B850	None directly.
Organs Monitored	Brain, lungs, heart, liver, kidneys, skin temperature	Identical
Hardware platforms supported	PC, iPad, iPhone	Identical
Generates clinical advisories	AlertWatch:OR Analyzes data from patient monitors and other sources and alerts when values exceed preset limits.	Identical
Re-display of vital sign data from primary monitors	Yes	Identical
Intended to replace primary monitors	No	Identical
Paging	Yes. For clinicians to page each other and for AlertWatch:OR to transmit alerts using the hospital-established paging system.	Yes. For clinicians to page each other and for AlertWatch:OB to transmit alerts using the hospital-established paging system.
Uses color to display clinical information		

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:OB 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:OR 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 first conducted a formative to identify and fix any problems with the usability study plan and AlertWatch:OB product. AlertWatch then recruited 17 users and conducted a summative usability study. The results of the study showed that users with minimal training were able to successfully perform critical tasks and use the device for its intended purpose – to clarify clinical information and support information access.
- **Default Limits and Thresholds**: AlertWatch, Inc. used a three-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.** When references were not available, AlertWatch sought out the opinion and confirmation of obstetricians and OB anesthesia physicians at the University of Michigan Health System. Each of these clinicians reviewed the limits, provided feedback, and reviewed the final results.
3. **External Experts.** AlertWatch obtained final review of the default limits from an external group of four anesthesiology and OB anesthesia experts. All approved the clinical limits.

- **IEC 60601-1-8**: A summary of how AlertWatch:OR 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:OB and the predicate AlertWatch:OR have the same intended use, namely to provide secondary monitoring of patients in the hospital environment. 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, 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:OB has been demonstrated to be substantially equivalent to the predicate AlertWatch:OR.