DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 15, 2016

Alertwatch LLC
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington Street
Suite 100
Alexandria, Virginia 22314

Re: K153335
Trade/Device Name: Alertwatch: OR
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: February 16, 2016
Received: February 18, 2016

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.

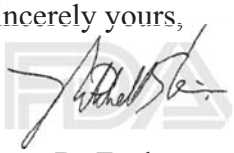
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153335

Device Name
AlertWatch: OR

Indications for Use *(Describe)*
AlertWatch:OR is intended for use by clinicians for secondary monitoring of patients within operating rooms. AlertWatch:OR combines data from networked physiologic monitors, anesthesia information management systems and patient medical records and displays them in one place. AlertWatch:OR can only be used with both physiological monitors and AIMS versions that have been validated by AlertWatch. Once alerted, you must refer to the primary monitor or device before making a clinical decision.

AlertWatch:OR is also intended for use by supervising anesthesiologists outside of operating rooms. Once alerted, the supervising anesthesiologist must contact the clinician inside the operating room or must return to the operating room before making a clinical decision. Once either clinician is alerted, they must refer to the primary monitor or device 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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) SUMMARY – K153335

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

Device Common Name:	Physiological Patient Monitor without arrhythmia detection or alarms
Device Trade Name:	AlertWatch:OR
Applicant:	AlertWatch, LLC 1600 Huron Pkwy, Bldg. 520, Ste. 2326 Ann Arbor, MI 48109
Contact:	Justin Adams, CEO AlertWatch, LLC Phone: 734-998-8344 Email: Justin.adams@alertwatch.com
Prepared by:	Donna-Bea Tillman Senior Consultant Biologics Consulting Group, Inc. Phone: 410-531-6542 Fax: 720-293-0014 Email: dtillman@bcg-usa.com
Date Prepared:	November 18, 2015
Classification Regulation:	21 CFR 870.2300 - Cardiac monitor (including cardiotachometer and rate alarm)
Panel:	Cardiovascular
Product Code:	MWI
Predicate Device:	K130401, AlertWatch: OR, AlertWatch, LLC

Indication for Use:

AlertWatch:OR is intended for use by clinicians for secondary monitoring of patients within operating rooms. AlertWatch:OR combines data from networked physiologic monitors, anesthesia information management systems and patient medical records and displays them in one place. AlertWatch:OR can only be used with both physiological monitors and AIMS versions that have been validated by AlertWatch. Once alerted, you must refer to the primary monitor or device before making a clinical decision.

AlertWatch:OR is also intended for use by supervising anesthesiologists outside of operating rooms. Once alerted, the supervising anesthesiologist must contact the clinician inside the

operating room or must return to the operating room before making a clinical decision. Once either clinician is alerted, they must refer to the primary monitor or device before making a clinical decision.

Device Description:

AlertWatch:OR is a display and secondary alert system used by the anesthesiology staff – residents, CRNA's, and attending anesthesiologists – to monitor patients in operating rooms. The purpose of the program is to synthesize a wide range of patient data and inform clinicians of potential problems that might lead to immediate or long-term complications. Once alerted, the clinician is instructed to refer to the primary monitoring device before making a clinical decision. AlertWatch:OR should only be connected to AIMS systems and physiologic monitors that have been validated for use with AlertWatch:OR. AlertWatch, LLC performs the validation for each installation site.

The purpose of this 510(k) is for marketing clearance of AlertWatch:OR 2.50 which includes minor modifications to some display views, user features, indicators and alerts as well as compatibility with the iPad and the iPhone.

Performance Data:

- **Human Factors Study:** The iPhone version of AlertWatch:OR has a different user interface than the desktop product. To better understand any potential usability issues that could interfere with the intended use of the product, AlertWatch performed a comprehensive human factors study. The iPad version did not require a human factors study, because the layout and input methodology was the same as the predicate version (assuming a touch screen PC in the operating room).
- **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 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 experts.
- **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.

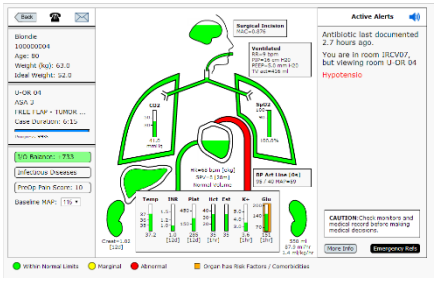
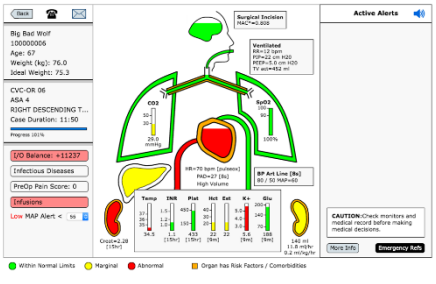
Substantial Equivalence:

Primary Predicate -The cleared AlertWatch:OR (K130401) is provided as a primary predicate device in terms of Indications for Use and technological characteristics.

Reference Device - Per the FDA Guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued July 28, 2104, the cleared Amcom CommTech Messenger (K112047) is provided as a reference device to support the use of paging to include alerts that originate from AlertWatch:OR.

The table below compares the key technological features of the subject device to the primary predicate device (AlertWatch: OR K130401).

	Predicate Device	**Proposed Device**
Device Name	AlertWatch:OR (v2.48)	AlertWatch:OR (v2.50)
510(k) number	K130401	K153335
Classification	MWI	MWI
Regulation	870.2300	870.2300
Indications for Use	AlertWatch:OR is intended for use by clinicians for secondary monitoring of patients within operating rooms. AlertWatch:OR combines data from networked physiologic monitors, anesthesia information management systems and patient medical records and displays them in one place. AlertWatch:OR can only be used with both physiological monitors and AIMS versions that have been validated by AlertWatch. Once alerted, you must refer to the primary monitor or device before making a clinical decision.	AlertWatch:OR is intended for use by clinicians for secondary monitoring of patients within operating rooms. AlertWatch:OR combines data from networked physiologic monitors, anesthesia information management systems and patient medical records and displays them in one place. AlertWatch:OR can only be used with both physiological monitors and AIMS versions that have been validated by AlertWatch. Once alerted, you must refer to the primary monitor or device before making a clinical decision. AlertWatch:OR is also intended for use by supervising anesthesiologists outside of operating rooms. Once alerted, the supervising anesthesiologist must contact the clinician inside the operating room or must return to the operating room before making a clinical decision. Once either clinician is alerted, they must refer to the primary monitor or device before making a clinical decision.
Intended Use environment	OR – referred to primary monitor for clinical decision.	OR – referred to primary monitor for clinical decision. The mobile AlertWatch application can be installed on a personal iPhone or used via safari on an iPad for use by supervising anesthesiologists outside of operating rooms, who are connected to the hospital

	Predicate Device	Proposed Device
		network.
Intended Users	Anesthesiologist, Resident, CRNA	Identical
Data server	AlertWatch:OR accesses physiologic data from the hospital network, and all other data from the AIMS database server.	Identical
Supported AIMS systems	GE Centricity 7.63	Centricity, version 7.6.3 Picis / Optum, version 421 iMDsoft / Metavision, version 5.46.44
Supported physiological monitors	GE Solar 9500 GE Carespan B850	Identical
Hardware platforms supported	PC	PC, iPad, iPhone
Generates clinical advisories	AlertWatch:OR Alerts analyzes data from patient monitors and other sources and alerts when values exceed preset limits.	AlertWatch:OR Alerts analyzes data from patient monitors and other sources and alerts when values exceed preset limits. There are been some changes to the content of these advisories (see Section 11.9 and 11.10)
Re-display of vital sign data from primary monitors	Yes	Yes
Intended to replace primary monitors	No	No
Paging	Yes. For clinicians to page each other using the hospital-established paging system.	Yes. For clinicians to page each other and for AlertWatch:OR to transmit alerts using the hospital-established paging system.
Uses color to display clinical information		

Substantial Equivalence Conclusion:

The subject AlertWatch:OR (v2.50) is modification of the previously cleared device (K130401) that adds several new features that do not alter the fundamental intended use of the device as a secondary monitor for patients in the operating room. The indications for use are identical to the predicate device.

The modified alerts and changes to the display of information, and the addition of an iPhone version, do not raise different questions of safety or effectiveness when compared to the primary predicate device. A Usability Study demonstrated that users were able to successfully complete critical tasks in a simulated use environment. Wireless coexistence testing demonstrated that the system could operate correctly in an environment with other wireless devices. Software verification testing demonstrated that the software met all requirements and performed as expected. Therefore, AlertWatch:OR (v2.50) can be found substantially equivalent to the previously cleared AlertWatch:OR (v2.48).