DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

February 7, 2014

AlertWatch LLC
c/o Donna-Bea Tillman
400 N. Washington Street
Suite 100
Alexandria, VA 22314 US

Re: K130401
Trade/Device Name: Alertwatch: OR
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II
Product Code: MHX
Dated: November 6, 2013
Received: November 8, 2013

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Owen P. Faris -S

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 on last page.

510(k) Number *(if known)*
K130401

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
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."

FEB - 7 2014

510(k) Summary

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

Device Common Name:	Physiological Patient Monitor with arrhythmia detection or alarms
Device Proprietary Name:	AlertWatch:OR
Submitter:	AlertWatch 1600 Huron Pkwy, Bldg. 520, Ste. 2326 Ann Arbor, MI 48109
Contact:	Donna-Bea Tillman Senior Consultant Biologics Consulting Group, Inc. Phone: 410-531-6542 Fax: 720-293-0014 Email: dtillman@bcg-usa.com
Date Prepared:	January 30, 2014
Classification Regulation:	21 CFR 870.1025
Panel:	Cardiovascular
Product Code:	MHX
Predicate Device:	K082583, Phillips MP90

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.

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, Inc. performs the validation for each installation site.

Performance Testing:
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. There were four parts to the verification process:

1. Verify the analysis output: Using constructed data, each of the rules/algorithms in the Software Requirements Specification were passed to the product's analysis component to determine that it produced the desired output.
2. Verify the data display: Similar to step 1. Using constructed data, verify that the web client produced the desired display for each of the test cases.
3. Verify the collectors: Determine that the Live Collector and the Data Collector return the correct data from the EMR.
4. Verify the product with historical data: Using a set of cases from actual patients, determine that the product works as designed.

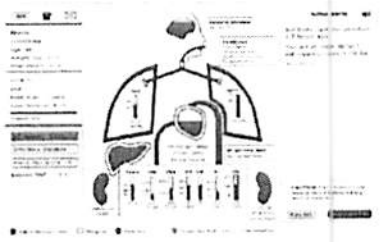
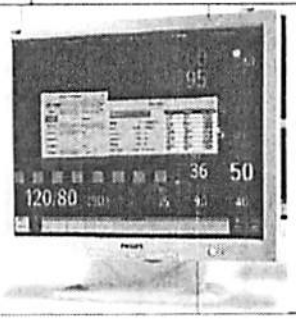
Validation was conducted to check the design and performance of the product, and included these steps:

1. Review the process and various inputs for creating the product design – the software requirements specification.
2. Review the software requirements specification for clinical accuracy.
3. Validate the clinical utility of the product by analyzing case outcomes.
4. Conduct a summative Human Factors study to demonstrate that the device meets user needs.

Substantial Equivalence:
The results of the verification and validation activities demonstrate that the AlertWatch:OR complies with its stated requirements and meets user needs and intended uses. Therefore, it can be found substantially equivalent to the MP90.

Table 1: Device Comparison Table

	Proposed Device	Predicate Device
Device Name	AlertWatch:OR	Philips MP90
510(k) number	Not Yet Assigned	K082583
Classification	MHX	MHX
Regulation	870.1025	870.1025
Indications for Use	AlertWatch: OR is intended for use by clinicians for secondary	Indicated for use by health care professionals whenever there is a

	monitoring of patients within operating rooms. AlertWatch:OR accomplishes this by aggregating data from networked physiologic monitors, anesthesia information management systems and patient medical records and displaying them at a central location. Once alerted, the clinician must refer to the primary monitoring device before making a clinical decision.	need for monitoring the physiological parameters of patients. Intended for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, X2, MPS, MP20, MP30, MP40, and MPSO are additionally intended for use in transport situations within hospital environments. The MP2, X2 and MPS are also intended for use during patient transport outside of a hospital environment.
Intended Use environment	OR	OR, Bedside
Intended Users	Anesthesiologist, CRNA	Anesthesiologist, Surgeon, Perfusionist
Data server	AlertWatch:OR accesses physiologic data from the hospital network, and all other data from the AIMS database server.	Philips IntelliVue Application Server accesses information from the hospital network, including radiology, pharmacy, laboratory and Hospital Information System data.
Re-display of vital sign data from primary monitors	Yes	Yes
Generates clinical advisories	AlertWatch:OR Alerts analyzes data from patient monitors and other sources and alerts when values exceed preset limits.	Advanced Event Surveillance feature analyzes data from patient monitors and alerts when values exceed preset limits.
Uses color to display clinical information		
Intended to replace primary monitors	No	No