January 4, 2018

Excel Medical Electronics, LLC
Lance Burton
General Manager
801 Maplewood Dr.
Suite 25
Jupiter, Florida 33458

Re: K171056
Trade/Device Name: WAVE Clinical Platform
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: November 30, 2017
Received: December 4, 2017

Dear Lance Burton:

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

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)*
K171056

Device Name
WAVE Clinical Platform

Indications for Use *(Describe)*
The WAVE Clinical Platform is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS).

The WAVE Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms, alarms, results and diagnostic information routed through the WAVE Clinical Platform from supported devices and systems. The WAVE Clinical Platform is intended for use in hospital or hospital type environments. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes:

- To remotely consult regarding patients' statuses;
- To remotely review other standard or critical near real-time patient data, waveforms, alarms, and results in order to utilize this information to aid in clinical decisions.

Warning: The WAVE Clinical Platform is intended to supplement and not to replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.

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
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
WAVE Clinical Platform

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for the use of the WAVE Clinical Platform.

1. **Date:** April 7, 2017

2. **SUBMITTED BY:**
Excel Medical Electronics, LLC
801 Maplewood Drive, Suite 25
Jupiter, Florida 33458

3. **CONTACT PERSON:**
Lance Burton
General Manager
Email: lance.burton@excel-medical.com
Phone: 866-573-8807
Fax: 561-748-8889

4. **DEVICE INFORMATION:** WAVE Clinical Platform

Device Information	
Device Proprietary Name:	WAVE Clinical Platform
Common or Usual Name:	Data Management, Visualization and Clinical Decision Support Software
Classification:	Class II Device
Product Code:	MWI
Regulation Number:	CFR 870.2300
Regulation Name:	Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Classification Name:	Cardiac Monitor (including cardiotachometer and rate alarm) Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)

Review Panel:	Part 870, Subpart B Cardiovascular Diagnostic Devices, Sec. 870.1425 Programmable Diagnostic Computer

5. **PREDICATE DEVICE:** COVIDIEN VITAL SYNC™ INFORMATICS MANAGER & VIRTUAL PATIENT MONITORING PLATFORM (K140339; MWI, OUG)

   INTENDED USE: "The Vital Sync™ Informatics Manager is software that is intended to route and store medical device data and device diagnostic information from supported devices to the Electronic Medical Record (eMR) and Clinical Information System (CIS).
   The Vital Sync™ Virtual Patient Monitoring Platform is a remote monitoring platform that displays physiologic data, waveforms and alarms routed through the Vital Sync™ Informatics Manager for supported devices. The Vital Sync™ Virtual Patient Monitoring Platform is intended to be used by healthcare professionals for the following purposes:
   • To remotely consult regarding a patient's status
   • To remotely review other standard or critical near real-time patient data, waveforms and alarms in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

   WARNING: The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform are intended to supplement and not to replace any part of the hospital's device monitoring. Do not rely on the Vital Sync™ Informatics Manager &Virtual Patient Monitoring Platform as the sole source of alarms."

Predicate Device Information	
Device Proprietary Name:	Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform
Classification:	Class II Device
510(k) Number:	K140339
Product Code:	MWI, OUG
Regulation Number:	CFR 870.2300
Regulation Name:	Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Classification Name:	Cardiac Monitor (including cardiotachometer and rate alarm) Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)

Review Panel:	Part 870, Subpart B Cardiovascular Diagnostic Devices, Sec. 870.1425 Programmable Diagnostic Computer

6. **DEVICE DESCRIPTION:** Excel Medical's WAVE Clinical Platform is a software platform that gathers and stores data from patient monitoring and other medical devices, hospital information systems, and clinical analytics data sources for near real-time and retrospective remote display for clinicians to use in clinical decision support. The WAVE Clinical Platform can also route and forward these data to third party systems.

   The WAVE Clinical Platform can utilize the hospital's existing network and hardware for installation and display on any device that is web-enabled. The WAVE Clinical Platform does not control any of the medical devices or systems it is connected with.

7. **INTENDED USE / INDICATIONS FOR USE:** The WAVE Clinical Platform is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS). The WAVE Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms, alarms, results and diagnostic information routed through the WAVE Clinical Platform from supported devices and systems. The WAVE Clinical Platform is intended for use in hospital or hospital type environments. The WAVE Clinical Platform is intended to be used by healthcare professionals for the following purposes:

   - To remotely consult regarding patients' statuses;
   - To remotely review other standard or critical near real-time patient data, waveforms, alarms, and results in order to utilize this information to aid in clinical decisions.

   Warning: The WAVE Clinical Platform is intended to supplement and not replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the WAVE Clinical Platform product as the sole source of alarms.

8. TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

	Predicate - Vital Sync Informatics Manager & Virtual Patient Monitoring Platform	**WAVE Clinical Platform**
Indications for Use	The ***Vital Sync Informatics Manager*** is software that is intended to route and store medical device data and device diagnostic information from supported devices to the Electronic Medical Record (EMR) and Clinical Information System (CIS). The ***Vital Sync Virtual Patient Monitoring Platform*** is a remote monitoring platform that displays physiologic data, waveforms and alarms routed through the ***Vital Sync Informatics Manager*** for supported devices. The ***Vital Sync Virtual Patient Monitoring Platform*** is intended to be used by healthcare professionals for the following purposes: • To remotely consult regarding a patient's status • To remotely review other standard or critical near real-time patient data, waveforms and alarms in order to utilize	The ***WAVE Clinical Platform*** is software intended to route, store, and display data, alarms, results and diagnostic information from medical devices, Electronic Medical Records (EMR), and Clinical Information Systems (CIS). The ***WAVE Clinical Platform*** is a remote monitoring platform that displays physiologic and clinically relevant data, waveforms, and alarms routed through the ***WAVE Clinical Platform*** from supported devices and data systems. The ***WAVE Clinical Platform*** is intended to be used by healthcare professionals for the following purposes: • To remotely consult regarding patients' statuses; • To remotely review other standard or critical near real-time and historical patient data, waveforms, alarms, and results in order to utilize

	this information to aid in clinical decisions and deliver patient care in a timely manner. WARNING: The ***Vital Sync Informatics Manager & Virtual Patient Monitoring Platform*** are intended to supplement and not to replace any part of the hospital's device monitoring. Do not rely on the ***Vital Sync Informatics Manager &Virtual Patient Monitoring Platform*** as the sole source of alarms.	this information to aid in clinical decisions and deliver patient care in a timely manner. WARNING: The ***WAVE Clinical Platform*** is intended to supplement and not to replace any part of the hospital's device monitoring or electronic data management systems. Do not rely on the ***WAVE Clinical Platform*** product as the sole source of alarms.
Device Regulatory Classification	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 & OUG	MWI
Device Class	II	II
510(k) Number	K140339	TBD
Other Technology Used	Standard computers, network, and WIFI technology	Standard computers, network, and WIFI technology
Host server	Uses hospital's existing server hardware or server pre-loaded with Vital Sync software and off the shelf operating system	Uses hospital's existing server hardware or server pre-loaded with the WAVE Clinical Platform software and off-the-shelf operating system

Data Storage	Hour to days of data is buffered and then archived to tape for indefinite storage until deleted	All data are archived to and indefinitely stored on disk drives until deleted
Where Used	Anywhere clinicians remotely consult on patients	Anywhere clinicians remotely consult on patients
Wireless	Yes, handheld display devices	Yes, handheld display devices
Ability to View Near Real-time Data	Yes	Yes
Synopsis of Functionality	Store, route and display patient monitor, EMR and CIS data, alarms, and smart alarms remotely to aid in clinical decisions and deliver patient care in a timely manner	Store, route and display patient monitor, EMR and CIS data, alarms, and smart alarms remotely to aid in clinical decisions and deliver patient care in a timely manner
Target Population/Demographics	ICU and ER patients that have Covidien physiological sensors attached.	In-hospital patients that have physiological sensors attached.

9. **Substantial Equivalence Discussion on Comparison to Predicate Device:**
Excel Medical's WAVE Clinical Platform and Covidien's Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform perform the same functions with no difference in how the devices are used. The WAVE Clinical Platform is a single medical device that performs the functions of (a) storing, (b) routing and (c) displaying data from patient monitors, EMR and CIS systems, and smart alarms. Covidien's two devices (Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform) perform these same functions. The WAVE Clinical Platform's data is displayed remotely to aid in clinical decisions and deliver patient care in a timely manner. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform's data is displayed remotely to aid in clinical decisions and deliver patient care in a timely manner. Excel

Medical's WAVE Clinical Platform data are archived to and indefinitely stored on disk drives until deleted. Covidien's Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform Hour to days of data is buffered and then archived to tape for indefinite storage until deleted. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform gathers ICU and ER patient data from Covidien physiological sensors. Excel Medical's WAVE Clinical Platform gathers data from in-hospital patients that have physiological sensors attached. These differences have no effect on how these devices are used. The patient's in-hospital location and the physiological sensors may be different, but Excel Medical's WAVE Clinical Platform and Covidien's Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform function and intended use are the same. Risk and Hazards are the determined to be the same for both devices.

10. Substantial Equivalence Discussion on Safety and Effectiveness:

There are three differences between Excel Medical's WAVE Clinical Platform and Covidien's Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform:

(1) The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform are essentially two products and the WAVE Clinical Platform is one product that perform the same functionality.

(2) The WAVE Clinical Platform gathers data from in-hospital patients that have physiological sensors attached. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform gathers ICU and ER patient data from Covidien physiological sensors. This is based on a business decision to include other manufacturer's devices and systems and is no difference in functionality or intended use of the product.

(3) The WAVE Clinical Platform has the ability to store a larger volume of data and made available online. Whereas, the Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform requires long term storage of data to be archived offline.

These differences have no effect on safety and effectiveness or the intended use for the device.

11. Summary of Technology Characteristics

Technology characteristics of the WAVE Clinical Platform and the Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform are determined to be the same. Both devices are software devices with client server architecture and support web-

enabled displays of data. Both software devices acquire and distribute data across general purpose hospital networks, both wired and wireless. Both devices have server software that run on general purposes server computer hardware and use data storage technology mediums widely available in hospitals. Both devices allow users to access and display data from web-enabled devices over wired and wireless general purpose networks. All of these technologies are proven and any risks and their mitigations are widely understood in hospital environments. The platforms have identical indications for use and both display parameters and waveforms from connected medical devices to a remote, web-enabled display.

12. Non-clinical Performance: Bench

Safety, efficacy and substantial equivalence was shown through system level tests, user interface verification, device compatibility verification, performance tests and safety testing. The WAVE Clinical Platform test results on non-clinical testing demonstrate the device is substantially equivalent to the predicate device - the Covidien Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform in terms of safety, features and performance. No new questions of safety and effectiveness have been raised.

13. Clinical Performance:

Not Applicable. Clinical evidence was not necessary to show substantial equivalence.

14. Conclusions from Non-clinical Performance Testing:

The WAVE Clinical Platform test results on non-clinical testing demonstrate the WAVE Clinical Platform is substantially equivalent to the predicate device - the Covidien Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform in terms of safety, features and performance.