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

May 26, 2015

Medical Informatics Corp
% David Makanani
Consultant
OMEDtech, LLC
1725 Signal Ridge Drive, Suite 150
Edmond, Oklahoma 73013

Re: K143304
Trade/Device Name: Sickbay™ 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: April 13, 2015
Received: April 14, 2015

Dear David Makanani,

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.

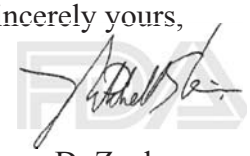
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indication for Use Statement

510(k) Number: K143304

Device Name: Sickbay™ Clinical Platform

Indications for Use:

The Sickbay Clinical Platform 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 Systems.

The Sickbay Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms and alarms routed through the Sickbay Clinical Platform for supported devices. The Sickbay Clinical Platform is intended to be used by healthcare professionals in a hospital setting 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 Sickbay Clinical Platform is intended to supplement and not to re-place any part of the hospital's device monitoring. Do not rely on the Sickbay Clinical Platform product as the sole source of alarms.

Note: Sickbay Clinical Platform product includes 3 Apps: Patient Monitoring App; Patient Alarm Data Monitor & Alarm Analytics Dashboard App.

Prescription Use: Yes AND/OR Over-The-Counter Use: NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

510(k)

Medical INFORMATICS

510(K) SUMMARY

Date	April 10th 2015
SUBMITTER	Medical Informatics Corp 6500 Main St. BioScience Research Collaborative Suite 1020G Houston TX 77030
CONTACT PERSON	Ralph Krog JD, Chief Compliance Officer Ralph.Krog@MedicalInformaticsCorp.com 713-370-3904
DEVICE NAME	Sickbay™ Clinical Platform
Classification	Device
Trade Name	Sickbay Clinical Platform
Common Name	Sickbay
Classification	Class II
Product Code	MWI, OUG
Review Panel	Part 870, Subpart B Cardiovascular Diagnostic Devices, Sec. 870.1425 Programmable diagnostic computer.
PREDICATE DEVICE:	COVIDIEN VITAL SYNC INFORMATICS MANAGER & VIRTUAL PATIENT MONITORING PLATFORM - 510(k)'s: K132604

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).

DEVICE DESCRIPTION: Medical Informatics Corp (MIC) has developed a software platform and analytics engine, Sickbay™, which gathers physiological data streams coming from patient monitoring devices and other clinical data sources. Medical Informatics Corp's software platform, Sickbay, captures patient data and enables near real-time display and analytics for clinicians to use in clinical decision support.

ENVIRONMENT OF USE: Sickbay Clinical Platform is intended to be used in a hospital environment.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

Parameter	Vital Sync	Sickbay 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. 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	The Sickbay Clinical Platform 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 Systems. The Sickbay Clinical Platform is a remote monitoring platform that displays physiologic data, waveforms and alarms routed through the Sickbay Clinical Platform for supported devices. The

Parameter	Vital Sync	Sickbay Platform
	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.	Sickbay Clinical Platform is intended to be used by healthcare professionals in a hospital setting 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 Sickbay Clinical Platform is intended to supplement and not to replace any part of the hospital's device monitoring. Do not rely on the Sickbay Clinical Platform as the sole source of alarms. Note: Sickbay Clinical Platform product includes 3 Apps: Patient Monitoring App; Patient Alarm Data Monitor & Alarm Analytics Dashboard App.
Functionality	Display patient monitor data remotely	Display patient monitor data remotely and store it for analysis.
Device Regulatory Classification	21 C.F.R. Part 870, Subpart B Cardiovascular Diagnostic	21 C.F.R. Part 870, Subpart B Cardiovascular Diagnostic

Parameter	Vital Sync	Sickbay Platform
	Devices, Sec. 870.1425 Programmable diagnostic computer.	Devices, Sec. 870.1425 Programmable diagnostic computer.
Product Code	MWI & OUG	MWI & OUG
Device Class	II	II
510(k) number	K132604	K143304
Technology	Standard computers, network and WIFI technology	Standard computers, network and WIFI technology
Data Storage	Hour to days of data is buffered and then archived on tape.	All physiological data is stored on disk drives forever, until deleted.
Wireless	Yes: handheld display devices	Yes: handheld display devices
Direct Sensor Contact	Covidien sensors supply data but are not part of this device.	Various hospital Monitors and sensors provide data but are not part of our device.
Optimum Range	Within the Hospital's secure WIFI network.	Within the Hospital's secure WIFI network.
Wireless vs Wired Function	WIFI from sensor to server, wired and WIFI out to handheld displays.	Both WIFI and wired from sensors to server and both WIFI and wired out.

Parameter	Vital Sync	Sickbay Platform
Software Main functionality	Patient information is transmitted wirelessly from bedside devices to the hospital's server The Vital Sync software, which resides on a hospital's server, takes this information and makes it viewable on any web-enabled device on the hospital network The information is formatted into HL7 protocol and written into the hospital EMR	Patient information is transmitted wired or wirelessly from bedside devices to the hospital's network The Sickbay Clinical Platform, which resides on a hospital's servers, takes this information stores it and makes it viewable on any web-enabled device on the hospital network Information from EMR (Lab, Meds and ADT records in HL7 format) is stored in Sickbay and available for redisplay.
Target population/ demographics	ICU and ER patients that have Covidien physiological sensors attached.	ICU and ER patients that have any physiological sensors attached.

WHY THE DIFFERENCES ARE NOT CRITICAL TO THE INTENDED USE OF THE DEVICE

Covidien has two devices (Vital Sync Informatics Manager & the Vital Sync Virtual Patient Monitoring Platform) performing two functions (route and store medical device data AND re-display physiologic data, waveforms and alarms). MIC has one device (Sickbay Clinical Platform) that performs the same two functions (route and store medical device data AND re-display physiologic data, waveforms and alarms). This difference has no effect on how the devices are used. Indeed both Vital Sync and Sickbay perform the same two general functions.

The Vital Sync Informatics Manager routes and stores data from supported devices to the Electronic Medical Record (EMR) and Clinical Information System. The Sickbay Clinical Platform routes and stores data from supported devices and from the Electronic Medical Record (EMR) and Clinical Information Systems. Covidien's Vital Sync is gathering data from Covidien bedside sensors and storing it in the Hospital's EMR. MIC's Sickbay gathers data from all sensors on the bedside from the hospital network (before they get to the EMR)

and stores data in its own Sickbay data base and Sickbay data repository or file set. This difference has no effect on how the devices are used; both devices gather and store medical data from other medical device sensors or monitors and re-display such data on supported devices. The set of medical sensors may differ, but the function and use of the two devices (Vital Sync and Sickbay) are the same.

WHY THE DIFFERENCES DO NOT AFFECT THE SAFETY AND EFFECTIVENESS OF THE DEVICE WHEN USED AS LABELED.

Covidien has two products performing two functions and MIC has one product performing the same two functions. This difference in structure or packaging has no effect on safety and effectiveness. The hazards are the same.

The difference in data storage (an EMR database versus Sickbay database) do not affect the safety and effectiveness of the product, because the reliability of data storage and retrieval technology is the same for both products. Sickbay's database does not replace or preclude use of an EMR.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of the two devices are the same. Both rely on general purpose computers, wired and wireless computer networks, and data storage technology. This technology is several generations old, well established, and its risks and mitigations are well understood. The only technological difference between Vital Sync and Sickbay is one of volume not technology. Sickbay uses more data storage because the data can be analyzed offline as well as redisplayed.

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

Sickbay Clinical Platform has been determined through engineering bench testing to support substantial equivalence with this device and the predicates.

TESTS CONDUCTED:

Performance Test	Applicable Standard	Results
Usability	IEC 62366	Complies
Software Life-Cycle	IEC 62304 AAMI TIR 45	Complies
AAMI/ANSI HE75	Human Factors	Complies
Health Informatics	IEEE 11073-10406	Complies

Performance Test	Applicable Standard	Results
Risk Management	ISO 14971	Complies
Medical Electrical Equipment – Collateral Standard: Gen. Requirements, Tests and Guidance for Alarm systems in Medical Electrical Equipment and Medical Electrical system	IEC 60601-1-8	Complies
Medical Electrical Equipment – Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment	IEC 60601-2-27	Complies

MIC referred to the following documents:

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm

General Principles of Software Validation; Final Guidance for Industry and FDA Staff
http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm085281.htm

Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm

Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design
http://www.fda.gov/RegulatoryInformation/Guidances/ucm259748.htm

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf

Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077812.htm

Guidance for Industry and FDA Staff - Addition of URLs to Electronic Product Labeling
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm228553.htm

This testing showed the Sickbay to meet applicable ISO, IEC and FDA safety and performance standards. And guidances.

PERFORMANCE TESTING – ANIMAL/CLINICAL

There has been no animal/clinical testing submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the Sickbay performs safely, as intended, and the comparative discussion of intended use, principle of operation, and technological characteristics, it is determined by MIC that the Sickbay is substantially equivalent to predicate devices.