November 14, 2016

Covidien
Timothy Holwick
Sr. Regulatory Specialist
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K160718
Trade/Device Name: Vital Sync Informatics Manager & Virtual Patient Monitoring Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, CBK, DQA, BZQ, CCK, MNR, MUD, OLW, OLT, OMC, ORT, DPS, DSI
Dated: October 21, 2016
Received: October 20, 2016

Dear Timothy Holwick:

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,

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

Enclosure
Indications for Use

Vital Sync™ Virtual Patient Monitoring Platform & Informatics Manager

Indications for Use (Describe)

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 Virtual Patient Monitoring Platform, 3rd Party Annunciation Systems, Electronic Medical Record (eMR) and Clinical Information System (CIS).

The Vital Sync™ Virtual Patient Monitoring Platform (VPMP) is a display system that provides visual and audible renderings of physiologic data, waveforms, alarms and alerts routed through the Vital Sync™ Informatics Manager from supported devices. The Vital Sync™ Virtual Patient Monitoring Platform is intended to be used by healthcare professionals in a hospital or hospital-type facility for the following purposes:

- To remotely view and review patient data, waveforms, alerts and alarm information from supported devices and clinical information systems to facilitate clinical management.
- To facilitate remote collaboration with other healthcare professionals regarding patient data from supported devices.
- To access additional processed parameters to facilitate patient monitoring, assessment and clinical management.
- To set and adjust alert thresholds on supported devices where this capability is not available on the device itself.
- To access data, waveforms and alerts from supported devices where these capabilities are not enabled or available on the device itself.

WARNING: The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform are notification systems and are not replacements for direct patient observation, patient assessment or clinical judgment.

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.

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510(K) SUMMARY

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 510k Summary for the use of the Vital Sync™ Virtual Patient Monitoring Platform & Informatics Manager

Submitted By: Covidien
6135 Gunbarrel Avenue
Boulder, CO 80301

Date: November 14, 2016

Contact Person: Timothy Holwick
Sr. Regulatory Specialist
(303) 305-2345

Proprietary Name: Vital Sync™ Virtual Patient Monitoring Platform & Informatics Manager

Common Name: Central Monitor

Device Classification Regulation: 21 CFR 870.2910

Device Primary Product Code: DRG

Device Secondary Product Codes: CBK, DQA, BZQ, CCK, MNR, MUD, OLW, OLT, OMC, ORT, DPS, and DSI.

Primary Predicate Device: Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform (K140339)

Secondary Predicate Device: GE Carescape Central Station (K133882)
Device Description

The subject Vital Sync™ Informatics Manager (IM) & Virtual Patient Monitoring Platform (VPMP) is a software only device that provides mobile and centralized remote monitoring. The Vital Sync™ Informatics Manager is intended to route and store medical device data from connected medical devices to the electronic medical record (eMR), clinical information system (CIS) and/or the Virtual Patient Monitoring Platform (VPMP). The Vital Sync™ Virtual Patient Monitoring Platform displays information received from the Informatics Manager on any web-enabled device.

The subject Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform routes and displays parameters, waveforms and alarms for the connected medical devices in near-real time. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform allows users to set up a new default alarm priority across device types and allows for institutions to modify alarm priorities per their internal protocols. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform provides for the setting or adjusting of thresholds on supported devices where this capability is not available on the device itself; the platform can also act the primary display for patient data and alerts where this capability is not available of enabled on the device itself. Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform includes Turn Time functionality. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform allows the user the capability, via the software, to perform simple calculations from processed parameters, or from manual input by the user.

Indications for Use/Intended Use

The subject Vital Sync™ IM & VPMP has similar indications for use as the predicate Vital Sync™ IM & VPMP and the GE Carescape Central Station.

The Indications for use are as follows:

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 Virtual Patient Monitoring Platform, 3rd Party Annunciation Systems, Electronic Medical Record (eMR) and Clinical Information System (CIS).

The Vital Sync™ Virtual Patient Monitoring Platform (VPMP) is a display system that provides visual and audible renderings of physiologic data, waveforms, alarms and alerts routed through the Vital Sync™ Informatics Manager from supported devices. The Vital Sync™ Virtual Patient Monitoring Platform is intended to be used by healthcare professionals in a hospital or hospital-type facility for the following purposes:
- To remotely view and review patient data, waveforms, alerts and alarm information from supported devices and clinical information systems to facilitate clinical management.

- To facilitate remote collaboration with other healthcare professionals regarding patient data from supported devices.

- To access additional processed parameters to facilitate patient monitoring, assessment and clinical management.

- To set and adjust alert thresholds on supported devices where this capability is not available on the device itself.

- To access data, waveforms and alerts from supported devices where these capabilities are not enabled or available on the device itself.

**WARNING:** The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform are notification systems and are not replacements for direct patient observation, patient assessment or clinical judgment.

**Technological Characteristics Comparison**

The subject Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform has identical features to the legally marketed predicate Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform with the addition of alarm normalization, threshold settings, turn time, derived parameters, manual data entry, and primary display and substantially equivalent features to the GE Carescape Central Station.

<table>
<thead>
<tr>
<th>Device characteristics</th>
<th>K160718</th>
<th>K140339</th>
<th>K133882</th>
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<td>Classification</td>
<td>DRG 870.2910</td>
<td>MWI 870.2300</td>
<td>DXJ 870.2450</td>
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<td>Secondary product codes</td>
<td>CBK, DQA, BZQ, CCK, MNR, MUD, OLW, OLT, OMC, ORT, DPS, and DSI</td>
<td>-</td>
<td>DXJ, CBQ, CBS, CCK, CBR, BZQ, CCL, NHQ, NHP, DSK, CCI, DSB, FLL, GWQ, DPT, DXN, BSE, NHO, DOA, JEG</td>
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<tr>
<td>Mobile Monitoring</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Patient Reports</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Zone Support</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Alarm Delays</td>
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<td>Yes</td>
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<tr>
<td>Intended Users</td>
<td>Clinicians</td>
<td>Clinicians</td>
<td>Clinicians</td>
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<tr>
<td>Alarm Display</td>
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<tr>
<td>Feature</td>
<td>Device 1</td>
<td>Device 2</td>
<td>Device 3</td>
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<tr>
<td>Waveform Display</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Manual Data Entry</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>Derived parameters</td>
<td>Yes</td>
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<tr>
<td>Ability to set alert thresholds</td>
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<td>eMR connectivity</td>
<td>Yes</td>
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<td>Yes</td>
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<td>Primary alerts for low acuity devices</td>
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<td>Alarm Normalization</td>
<td>Yes</td>
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<tr>
<td>Turn Timer</td>
<td>Yes</td>
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</tbody>
</table>

**Substantial Equivalence – Non-Clinical Evidence**

Safety, efficacy and substantial equivalence was shown through system level verification, user interface verification and usability validation. Testing was also conducted to ensure data passes over communication networks with consistency and integrity. Network factors such as outages and latency were addressed and/or mitigated through a risk-based approach. The results of the tests show that the subject Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform can be considered substantially equivalent to the legally marketed predicates.

**Substantial Equivalence – Clinical Evidence**

N/A – Clinical evidence was not necessary to show substantial equivalence

**Substantial Equivalence – Conclusions**

Substantial equivalence is shown through systems level testing, user interface testing, and usability validation. The subject Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform has identical features to the legally marketed predicate Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform with the addition of alarm normalization, threshold settings, turn time, derived parameters, manual data entry, and primary display and substantially equivalent features to the Ge Carescape Central Station.

No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent.

The term "equivalence" as used in this document is limited to the definition found in the Federal Food, Drug, and Cosmetic Act, 21 CFR 807, Subpart E, and relates only to whether the proposed device may be marketed without prior reclassification or clinical approval. This submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement law suit or any other patent matters.