



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

June 24, 2016

Philips Medical Systems  
Theresa Poole  
Regulatory Specialist  
3000 Minuteman Road  
Andover, Massachusetts 01810

Re: K161164

Trade/Device Name: CareEvent  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)  
Regulatory Class: Class II  
Product Code: MSX, OUG  
Dated: April 14, 2016  
Received: April 25, 2016

Dear Theresa Poole:

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.

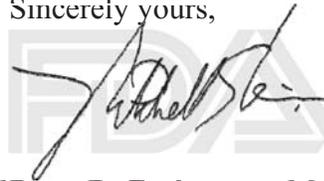
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K161164

Page 1 of 1

Device Name  
CareEvent

### Indications for Use (Describe)

The intended use of Philips CareEvent is to deliver supplemental medical device data associated with physiological alarms, technical alarms, clinical notifications, nurse call alarms and informational messages to a healthcare professional's end device. The user may receive visual or audible notifications, and/or other message notification types based on the communicator in use.

Philips CareEvent is a component of a distributed alarming system. It does not generate the alarm, alter the behavior of the alarm-generating system, replace the alarming system that generates the alarms, nor is it intended to provide real-time information, therefore the device producing the alarm or event remains the primary notification system. Philips CareEvent provides confirmed delivery features when it is used with the Philips CareEvent mobile application on Philips-approved devices. The Philips CareEvent mobile application either communicates alarm information that is sent from the Philips CareEvent server, or the user is notified that communication is not possible. Receipt of alarm messages or events by all other external devices is not confirmed and delivery to the end device is not guaranteed.

Rx Only

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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

### 510(k) Summary Philips CareEvent release B.01

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92(c).

Date Prepared: 23 June 2016

#### I. Submitter's name and address

Manufacturer: Philips Medical Systems  
3000 Minuteman Road  
Andover, MA 01810 USA

Contact Person: Theresa Poole  
Regulatory Affairs Specialist  
Philips Medical Systems  
3000 Minuteman Road, MS0480  
Andover, MA 01810-1099  
  
Tel: 978 659 7621  
Fax: 978 685 5624  
Email: [theresa.poole@philips.com](mailto:theresa.poole@philips.com)

#### II. Device information

Device Name: CareEvent  
Common Name: Communication System  
Classification panel: 74 - Cardiovascular

Classification names are as follows:

Classification	ProCode	Description
870.2300, II	MSX	System, Network and Communication, Physiological Monitors
880.6310, I	OUG	Medical Device Data System

#### III. Predicate device information

Trade name: CareEvent  
Manufacturer: Philips Medical Systems  
510(k) clearance: K142935  
Classification name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)  
Device class: Class II  
Classification regulation: 21 CFR 892.2300  
Classification panel: Cardiovascular  
Product code: MSX

## 510(k) Summary

### IV. Device Description

The CareEvent solution is designed to provide healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events).

### V. Intended use/ Indications for Use

The Philips CareEvent software application change in the intended use wording was initiated to clarify the previous predicate intended use statement. The Philips CareEvent software application release B.01 has the intended use statement listed below.

The intended use of Philips CareEvent is to deliver supplemental medical device data associated with physiological alarms, technical alarms, clinical notifications, nurse call alarms and informational messages to a healthcare professional's end device. The user may receive visual or audible notifications, and/or other message notification types based on the communicator in use.

Philips CareEvent is a component of a distributed alarming system. It does not generate the alarm, alter the behavior of the alarm-generating system, replace the alarming system that generates the alarms, nor is it intended to provide real-time information, therefore the device producing the alarm or event remains the primary notification system. Philips CareEvent provides confirmed delivery features when it is used with the Philips CareEvent mobile application on Philips-approved devices. The Philips CareEvent mobile application either communicates alarm information that is sent from the Philips CareEvent server, or the user is notified that communication is not possible. Receipt of alarm messages or events by all other external devices is not confirmed and delivery to the end device is not guaranteed.

Rx Only

### VI. Comparison of Technological Characteristics with the Predicate Device

Key Characteristic	Predicate Device CareEvent (K142935)	Subject Device CareEvent B.01	Comments
Intended Use/Indications for Use Sentence by Sentence comparison	S1: The intended use of the CareEvent solution is to provide healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events).	S1: The intended use of Philips CareEvent is to deliver supplemental medical device data associated with physiological alarms, technical alarms, clinical notifications, nurse call alarms and informational	S1: Clarification of timing, what type of information and to where.

## 510(k) Summary

	<p>S2: The product can route all of subsets of this information to selective remote devices such as pagers, phones, or marquees.</p> <p>S3-5: Receipt of alarm messages or events by the external device, is not confirmed and delivery to the end device is not guaranteed.</p> <p>The primary alarm notification is the device producing the alarm or event.</p> <p>This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.</p>	<p>messages to a healthcare professional's end device.</p> <p>S2: <i>The user</i> may receive visual or audible notifications, and/or other message notification types based on the communicator in use.</p> <p>S3-5: Philips CareEvent is a <i>component of</i> a distributed alarming system.</p> <p>It does not generate the alarm, alter the behavior of the alarm-generating system, replace the alarming system that generates the alarms, nor is it intended to provide real-time information, therefore the device producing the alarm or event remains the primary notification system.</p> <p>Philips CareEvent provides confirmed delivery features <i>when it is used with the Philips CareEvent mobile application on Philips-approved devices.</i></p>	<p>S2: Changed focus from product function to user experience. Clarified types of notifications. Stated it is dependent on end device in use (communicator) aligned with IEC 80001 terminology.</p> <p>S3-5: Removed entirely S3 from Predicate Intended use.</p> <p>Replaced with clarification of role CareEvent plays in a Distributed alarm system.</p> <p>Removed term secondary used in Predicate, it is not a standardized term.</p> <p>S6: Removed redundancy of the</p>
--	---	--	--

## 510(k) Summary

	<p>S6: The CareEvent mobile application software provides healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). Receipt of alarm messages or events by the external mobile device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.</p> <p>Rx Only</p>	<p>S6: The Philips CareEvent mobile application either communicates alarm information that is sent from the Philips CareEvent server, or the user is notified that communication is not possible.</p> <p>S7: Receipt of alarm messages or events by all other external devices is not confirmed and delivery to the end device is not guaranteed.</p> <p>Rx Only</p>	<p>predicate intended use for the CareEvent mobile application.</p> <p>Replaced it with clear definition of the role the mobile application plays in the distributed alarm system and confirmed delivery.</p> <p>S7: Added from predicate device to clarify that only Philips approved devices are different from the predicate.</p> <p>Same</p>
Target Patient Population	As determined by the Philips patient monitors in use at the facility.	Same	
Users	Trained health care professionals	Same	
Device Software	Unchanged, as previously cleared	<ol style="list-style-type: none"> <li>1. Allow one-way context sharing from CareEvent to MobileCaregiver.</li> </ol>	<ol style="list-style-type: none"> <li>1. When in CareEvent Mobile Application, allows user to open the Mobile CareGiver Application, if</li> </ol>

## 510(k) Summary

		<ol style="list-style-type: none"> <li>2. Text messaging capability within the CareEvent system via the CareEvent mobile application.</li> <li>3. Add user button on the CareEvent mobile application to Accept/Reject a delegation request when received.</li> </ol>	<p>installed on the same mobile device. Mobile CareGiver is a view of data from the PIIC iX central station.</p> <ol style="list-style-type: none"> <li>2. Provides users an alternative for team communication.</li> <li>3. Enables additional user control, if a user is not able to accept ownership of alerts from another device, they can intentionally reject the request.</li> </ol>
Technological Characteristics	Unchanged, as previously cleared.	Same	
Device Hardware is specified by Philips	Off the Shelf PC and other ITE equipment, specification available or can be ordered from Philips.	Same.	
Device Accessories	CareEvent Mobile Application	Same	
Care and Cleaning	Not applicable, software device.	Same	
Device safety and environmental specifications	Not applicable, software	Same	

**VII. Performance Data**

The following performance data were provided in support of the substantial equivalence determination:

**Summary of Non-clinical testing**

No performance standards have been issued under the authority of Section 514. The Philips CareEvent software Release B.01 was tested in accordance with Philips verification and validation processes. Quality Assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validations

**Summary of Clinical Testing**

Clinical Performance testing for Philips CareEvent software application Release B.01 was not performed, as there were no new clinical applications that had hazards or risk mitigations that required a clinical performance testing to support equivalence.

**Conclusions drawn from the Non-clinical and Clinical testing**

Verification, validation, and testing activities, where required to establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate are performed. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The Philips CareEvent software application Release B.01 meets all defined reliability requirements and performance claims.

**VIII. Conclusion**

Philips CareEvent software application Release B.01 is substantially equivalent to the predicate device Philips CareEvent software application (K142935) in terms of design features, fundamental scientific technology, safety and effectiveness. The change in the intended use was initiated to clarify the previous predicate intended use statement. Additionally, substantial equivalence was demonstrated with non-clinical performance testing, which complied with the requirements specified in the international and FDA-recognized consensus standards. The non-clinical performance tests provided in this 510(k) premarket notification demonstrate that the subject device is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.