DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2016

Philips Medical Systems
Ms. Mary Kruitwagen
Quality Assurance And Regulatory Affairs
3000 Minuteman Rd
Andover, Massachusetts 01810-1099

Re: K160951
Trade/Device Name: Philips Efficia CMS200 Central Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Network And Communication Physiological System
Regulatory Class: Class II
Product Code: MSX
Dated: March 28, 2016
Received: April 5, 2016

Dear Ms. Mary Kruitwagen,

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,

Shawn W. Forrest -S
2016.05.05 14:45:52 -04'00'

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)*

K160951

Device Name
Philips Efficia CMS200 central monitoring system

Indications for Use *(Describe)*
The Efficia CMS200 central monitoring system is intended for use by healthcare professionals for central viewing of physiologic waves, parameters, and trends from other networked medical devices (patient monitors and vital signs monitors) for multiple patients. It provides secondary operator notification of alarms from other networked medical devices. It provides for the retrospective review of alarm conditions, physiologic waves and parameters from multiple patients. The intended use of the printer, when present, is to provide hardcopy text, graphics, and wave data. The Efficia CMS200 may provide for connection and information exchange to external systems. The Efficia CMS200 is intended for use in hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.

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.

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Efficia CMS200 Central Monitoring System 510(k) Summary

Preparation Date	March 28, 2016
Submission Type:	Special 510(k)
Regulatory Information	
Classification	MSX
Additional Classifications	MHX, DSI, DPS, NSX
Common/ Usual Name	Central station
Trade Name	Philips Efficia
Proprietary Name	Efficia CMS200 Central Monitoring System
Models (with Reference numbers)	CMS200 (863352) with CMS200 software (S863352)
Device Sponsor	Philips Medical Systems, 3000 Minuteman Rd, Andover, MA, USA, 01810-1099
Device Owner	Philips Medical Systems, 3000 Minuteman Rd, Andover, MA, USA 01810-1099
Establishment Registration number:	1218950
Sponsor/Manufacturer/Owner/Operator:	1217116
Contact	Mary Kruitwagen Philips Medical Systems, 3000 Minuteman Rd, Andover, MA, USA, 01810-1099 Phone: (978) 659-4932 Fax: 978-659-7323 mary.kruitwagen@philips.com
Alternate contact	Greg Li Philips Medical Systems, 3000 Minuteman Rd,

Andover, MA 01810-1099 USA
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Fax: 978-659-7323
Email: greg.li@philips.com

Device Classification:
The primary classification procode is: MSX

The product codes and individual classification monographs applicable to the subject devices are listed below:

Device Panel	Classification	ProCode	Description
Cardiovascular	870.2300, II	MSX	System, Network and Communication, Physiological Monitors
	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	870.1110, II	DSJ	Alarm, Blood Pressure
	870.2340, II	DPS	Electrocardiograph
General Hospital	No Classified	NSX	software, transmission and storage, patient data

The predicate device for this subject device is:

K131032 08/16/2013 Philips SureSigns Central

Device Description

The subject Efficia CMS200 Central Monitoring System is comprised of medical device software, CMS200 software, model S863352, which is installed on a PC platform. The subject Efficia CMS200 includes S863352, the PC and peripherals. The Efficia CMS200 software is not marketed separately.

The subject Philips Efficia CMS200 Central Monitoring System is a central station. It provides continuous remote monitoring of up to 32 beds. It obtains data from networked patient monitors and provides centralized viewing of waveforms, numeric data and alarms from all the connected beds. It is providing secondary alarm notification. It allows for retrospective data review. It can transfer data to an electronic medical record system (EMR).

Fundamental Scientific Technology:

The subject Philips Efficia CMS200 Central Monitoring System (863352) is a rebranding of the predicate Philips SureSigns Central (863291) (K131032). The fundamental technology is the same between both. The subject Efficia CMS200 medical device software S863352 like the predicate SureSigns Central medical device software S863291 (K131032), uses the same operating system Microsoft Windows 7 Embedded. The development process and development tools are the same with both software developments. The software architecture and workflow is the same. The retrospective data is stored in a database within the PC. The database structure of the predicate device was LINUX while the subject device uses SQL Server database which requires an additional memory card in the PC.

It has the same basic functionality, features and functions as the previously cleared software for the predicate SureSigns Central (K131032). It uses the same GUI as the predicate device. Like the predicate device, the subject Efficia CMS200 provides connectivity to the Philips SureSigns VM Series patient monitors (K123900). Additionally the Efficia CMS200 provides connectivity to the Efficia CM Series Patient Monitors (CM10, CM12, CM100, CM120 and CM150) (K151812). This

includes the waveforms, numeric data and alarms of the measurements of Efficia CM patient monitors (K151812) including Masimo SET and Masimo rainbow measurements, Cardiac Output (C.O.), Acoustic Respiration (RRa), ST Segment and up to 12 leads of ECG.

Enhancements made to the subject device include the following software changes:

- Adding full disclosure to all waveforms for 240 hours. The predicate device stored one ECG waveforms for 240 hours.
- Stores Manual Events in the alarm history that are initiated at the Efficia CM Series Patient Monitor by the user
- Patient window increased number of displayed waved to 12 waves. The predicate allowed 8 waves in patient window.
- Additionally alarm logs are available to service personnel which include the time of the alarm and alarm reset, time of any button pushes that counteract the alarm, time of any failure of the measurement hardware and if the monitor is dropped from the network or the bedside. The predicate did not have an alarm log.

Like its predicate, the subject software (S863352) complies with the requirements for software (IEC 62304) and usability (IEC 62366) along with the system requirements for Medical Electrical Equipment standards when connected to the compatible patient monitors. No new issues of safety and effectiveness have been introduced with the changes of this submission.

The hardware on which the subject software will be shipped is the same as or similar to that used for the predicate device. The subject Efficia CMS200, uses the same license key, PC, display and network card as the predicate. The PC includes an additional memory card. The keyboard and mouse have been replaced with an updated version with the same specification. The network switch is the same. The printer is a substantial equivalent printer. The subject hardware complies with the regulations and requirements for information technology equipment.

Performance Data:

Performance data supports that the subject device performances to the same level of performance as the predicate device. The clinical preference testing supports that the customer requirements are met. The subject devices are in compliance with the following standards:

IEC 62304	IEC 62366

Additionally, the system requirements of the following standards are met when tested with the subject device Efficia CMS200 and the compatible patient monitors.

IEC 60601-1	IEC 60601-2-27	ISO 80601-2-55
IEC 60601-1-2	IEC 80601-2-30	ISO 80601-2-56
IEC 60601-1-6	IEC 60601-2-34	ISO 80601-2-61
IEC 62366 included IEC 62304	IEC 60601-2-49	ANSI/AAMI EC-13
IEC 60601-1-8		

The clinical evaluation included a literature search and a clinical user preference study. As the changes between the predicate and the subject device did not affect the GUI, it was determined no usability study was warranted. The clinical user preference study results did not yield any safety issues and only two enhancement requests. The device was well accepted. The clinical evaluation additionally found no trends.

Substantial Equivalence statement:

The subject Efficia CMS200 Central Monitoring System is a rebranding of the Philips SureSigns Central, reference 863291 with medical software S863291 (K131032). It has the same basic functionality as the previously cleared software for the predicate SureSigns Central (K131032). Like the predicate device, the subject Efficia CMS200 provides connectivity to the Philips SureSigns VM Series patient monitors (K123900). Additionally the Efficia CMS200 provides connectivity to the Efficia CM Series Patient Monitors (CM10, CM12, CM100, CM120 and CM150) (K151812).

While the predicate SureSigns Central was cleared to allow connectivity to 64 connected patient monitors, the subject Efficia CMS200 will provide connectivity to only 32 patient monitors. The subject Efficia CMS200 will display the same waveforms, numeric data and alarms as the predicate SureSigns central, and display the waveforms, numeric data and alarms of the measurements of Efficia CM patient monitors including Masimo SET and Masimo rainbow measurements, Cardiac Output (C.O.), Acoustic Respiration (RRa) and up to 12 leads of ECG.

The subject Efficia CMS200, like its predicate, allows for retrospective data review of alarms, tabular trends, graphical trends and full disclosure of each patients monitoring information. The database structure of the predicate device was LINUX while the subject device uses a SQL Server database. Both subject and predicate devices allowed for the data to be printed to a printer. Both subject and predicate allow for bidirectional communication of admit and discharge procedures, alarm silence, alarm limits adjustments, and NBP start/stop.

The subject software (S863352), like its predicate, has an operating system of Microsoft Windows 7 Embedded. The CMS200 software was developed using the same tools as the predicate. The software architecture and workflow is the same. The subject software (S863352) complies with the requirements for software (IEC 62304) and usability (IEC 62366) along with the system requirements for Medical Electrical Equipment standards when connected to the compatible patient monitors.

From a hardware perspective, the subject Efficia CMS200, uses the same license key, PC with network card and display. The keyboard and mouse have been replaced with an updated version with the same specification. The network switch is the same. The printer is a substantial equivalent printer. The subject hardware complies with the regulations and requirements for information technology equipment.

There have been no adverse events for the predicate Philips SureSigns Central. And for the countries where the Efficia CMS200 is already marketed, there have been no reported adverse events.

Intended Use /Indications for Use::

The Efficia CMS200 central monitoring system is intended for use by healthcare professionals for central viewing of physiologic waves, parameters, and trends from other networked medical devices (patient monitors and vital signs monitors) for multiple patients. It provides secondary operator notification of alarms from other networked medical devices. It provides for the retrospective review of alarm conditions, physiologic waves and parameters from multiple patients. The intended use of the printer, when present, is to provide hardcopy text, graphics, and wave data. The Efficia CMS200 may provide for connection and information exchange to external systems. The Efficia CMS200 is intended for use in hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.

Conclusion:

The subject Efficia CMS200 Central Monitoring System utilizes the same fundamental scientific technology as the predicate device on the market. The hardware platform is the same as or similar to that of the predicate device the predicate Philips SureSigns Central. The energy source is electrical like the predicate. Both the predicate and subject devices have the same

software architecture and software workflow. The subject Efficia CMS200 uses a SQL Server database for retrospective data storage unlike the predicate which used LINUX database. The user interface is the same between subject and predicate devices.

The subject Efficia CMS200 has the same level of safety and essential performance as compared to the predicate device when reviewing the totality of the device history file. It is our assessment that the subject device demonstrates that it are substantially equivalent to the identified predicate and has the same level of safety and effectiveness.