



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

January 26, 2016

Philips Medical Systems  
Mary Kruitwagen  
QA and Regulatory Affairs  
3000 Minuteman Road  
Andover, MA 01810-1099

Re: K151812

Trade/Device Name: Philips Efficia CM10 863301, Philips Efficia CM12 863303, Philips Efficia CM100 863300, Philips Efficia CM120 863302, Philips Efficia CM150 863304

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)

Regulatory Class: Class II

Product Code: MHX, MLD, DSJ, DSK, DXN, DRT, DQA, DSA, FLL, CCK, BZQ

Dated: December 16, 2015

Received: December 21, 2015

Dear 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

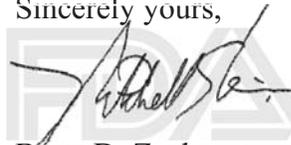
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, faint, light-colored 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)  
K151812

Device Name  
Philips Efficia CM10 863301, Philips Efficia CM12 863303, Philips Efficia CM100 863300, Philips Efficia CM120 863302  
Philips Efficia CM150 863304

Indications for Use (Describe)

The Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors are intended for monitoring, analysis, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.

Parameter (patient types): ECG (Adult, Pediatric, Neonatal); Respiration - Impedance (Adult, Pediatric, Neonatal); Respiration - RRA (Adult); Respiration - awRR (Adult, Pediatric, Neonatal); NBP (Adult, Pediatric, Neonatal); SpO2 (Adult, Pediatric, Neonatal); SpHb (Adult, Pediatric); SpCO (Adult, Pediatric); Temperature (Adult, Pediatric, Neonatal); CO2 (Adult, Pediatric, Neonatal); IBP (Adult, Pediatric, Neonatal); Cardiac Output (Adult, Pediatric); Arrhythmia (Cardiotach) (Adult, Pediatric, Neonatal); Arrhythmia (Basic) (Adult, Pediatric); Arrhythmia (Advanced) (Adult, Pediatric); ST segment Analysis (Adult);

Contraindications: Not for transport outside the healthcare facility

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."*

# Efficia CM10, CM12, CM100, CM120 and CM150 Patient Monitors 510(k) Summary

Preparation Date	September 18, 2015
Submission Type:	Traditional 510(k)
Regulatory Information Classification	Physiological Monitor, Patient Monitor
Common/ Usual Name	Multi-parameter Patient monitor
Trade Name	Philips Efficia
Proprietary Name	Efficia CM10 Efficia CM12 Efficia CM100 Efficia CM120 Efficia CM150
Models (with Reference numbers)	CM10 (863301) CM12 (863303) CM100 (863300) CM120 (863302) CM150 (863304)
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

Peter Schipelliti,  
Philips Medical Systems, 3000 Minuteman Rd,  
Andover, MA 01810-1099 USA  
Email: peter.schipelliti@philips.com  
Phone: (978) 659-4744  
Fax: 978-659-7323

Device Classification:

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

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	870.1025, II	MLD	Monitor, St Segment With Alarm
	870.1110, II	DSJ	Alarm, Blood Pressure
	870.1110, II	DSK	Computer, Blood Pressure
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiometer & Rate Alarm)
	870.2700, II	DQA	Oximeter
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector
	890.1175, II	IKD	cable, electrode
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas,
	868.2375, II	BZQ	Monitor, Breathing Frequency

Device Description

The subject Philips Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors are a family of physiological vital signs monitors. The monitors come with a variety of display sized (10 inch, 12 inch or 15 inch) and with a variety of measurements, some optional. The monitors primarily run on AC power with a secondary battery. The exterior material is the same as the primary predicate devices.

Fundamental Scientific Technology:

The subject Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors include the following parameters (some optional): ECG, Respiration, NBP, SpO<sub>2</sub>, SpHb, SpCO, Temperature, Invasive Blood Pressure, Cardiac Output, Arrhythmia Analysis, ST-Segment monitoring, and CO<sub>2</sub> monitoring.

- The ECG algorithm is a Philips algorithm which is well established in the marketplace and is used in the primary predicate devices (K123900).
- Respiration rate can be measured through impedance technology, from capnography or via acoustic respiration. The Impedance respiration algorithm is the same algorithm as used in the primary predicate devices (K123900).
- Respiration from capnography, shown as awRR, is either from Microstream side-stream from the Oridion algorithm or main stream CO<sub>2</sub>.
  - The Sidestream method is the same as in the primary predicate (K123900). The main stream CO<sub>2</sub> including respiration is from Respirationics.
  - The algorithm of the respirations from the mainstream CO<sub>2</sub> is from Respirationics M2105A sensor (K042601 and K050762) and is used unchanged in the subject devices.
  - The acoustic respirations (awRR) measurement is achieved via the Masimo rainbow Set using their algorithm unchanged and previously cleared (K100428).

- The NBP algorithm is proprietary Philips algorithm and is the same algorithm as in the primary predicate device (K123900).
- The subject devices offer two different SpO<sub>2</sub> algorithms. The default SpO<sub>2</sub> algorithm is a Philips proprietary algorithm and is unchanged from the primary predicate device (K123900). Optionally, the user can select the Masimo Set or Masimo rainbow Set. This option uses Masimo's algorithm unchanged from its predicate (K100428). SpHb and SpCO are part of Masimo's algorithm and are implemented unchanged from the Masimo predicate.
- The temperature measurement is similar algorithm of primary predicate (K123900).
- The invasive blood pressure algorithm is a Philips algorithm which is unchanged from that in the primary predicate device (K123900).
- The arrhythmia algorithm and the ST-Segment analysis algorithm used the Philips ST/AR algorithm and incorporate a subset of the STAR algorithm as cleared by K101521.

Performance data supports that the subject devices performance to same or better level of safety and effectiveness as the predicate devices. Clinical user preference and usability studies support that the customer requirements are met. The subject devices are in compliance with the following standards:

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 predicates for the subject devices are:

K123900	03/19/2013	Philips SureSigns VM Series Patient Monitors
K050762	04/22/2005	Philips MP20, MP30, MP40, MP50, MP60, MP70 MP90 IntelliVue Patient Monitor
K042601	11/19/2004	Respironics CAPNOSTAT 5 CO <sub>2</sub> sensor
K100428	07/09/2010	Masimo Rainbow SET® Radical 7R CO-Oximeter and Accessories
K101521	07/25/2010	Philips ST/AR ST and Arrhythmia Software, Release K.0

Primary 510(k) Predicate

K123900	03/19/2013	Philips SureSigns VM Series Patient Monitors
---------	------------	----------------------------------------------

Indications for Use:

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The intended uses are for monitoring, analysis, recording and alarming of multiple physiological parameters in healthcare environments for patient types listed below. Additionally, the monitor may be used in transport situations within a healthcare facility.

Parameter	Patient Types		
	Adult	Pediatric	Neonatal
ECG	√	√	√
Respiration - Impedance	√	√	√
Respiration - RRa	√		

Parameter	Patient Types		
	Adult	Pediatric	Neonatal
Respiration - awRR	√	√	√
NBP	√	√	√
SpO <sub>2</sub>	√	√	√
SpHb	√	√	
SpCO	√	√	
Temperature	√	√	√
CO <sub>2</sub>	√	√	√
IBP	√	√	√
Cardiac Output	√	√	
Arrhythmia (Cardiotach)	√	√	√
Arrhythmia (Basic)	√	√	
Arrhythmia (Advanced)	√	√	
ST segment Analysis	√		

Contraindications: Not for transport outside the healthcare facility

#### Conclusion

The subject Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors utilize the same fundamental scientific technology as the predicate devices on the market. The energy source is electrical with secondary battery back like the primary predicate. The subject Efficia CM10, CM12, CM100, CM120 and CM150 patient monitors use the same algorithms and have the similar performance to their predicates. They have the same or better level of safety and essential performance as compared to their predicate devices when reviewing the data of the totality of the device history file. It is our assessment that the subject devices demonstrate that they are substantially equivalent to the identified predicates and have the same level of safety and effectiveness.