



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

October 27, 2015

Philips Medical Systems  
Ms. Mary Kruitwagen  
QA and Regulatory Affairs  
3000 Minuteman Rd  
Andover, Massachusetts 03104-1099

Re: K152363  
Trade/Device Name: Value Care Cuff Large Adult, Value Care Cuff Adult XI (extra Long), Value Care Cuff Adult, Value Care Cuff Small Adult, Value Care Cuff Pediatric, Value Care Cuff Infant, Efficia Adult NIBP Airhose, 3 M, Efficia Adult NIBP Air Hose, 1.5 M  
Regulation Number: 21 CFR 870.1120  
Regulation Name: Blood Pressure Cuff  
Regulatory Class: Class II  
Product Code: DXQ  
Dated: August 14, 2015  
Received: August 20, 2015

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,

**Bram D. Zuckerman -S**

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)

K152363

Device Name

Value Care Cuff Large Adult, Value Care Cuff Adult XI (extra Long), Value Care Cuff Adult, Value Care Cuff Small Adult, Value Care Cuff Pediatric, Value Care Cuff Infant, Efficia Adult NIBP Airhose, 3 M, Efficia Adult NIBP Air Hose, 1.5 M

Indications for Use (Describe)

Philips multi-patient and single-patient cuffs are intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the non-invasive measurement of infant, pediatric, and adult human blood pressure.

Philips air hoses are intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the noninvasive measurement of neonatal, pediatric, and adult human blood pressure.

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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## Philips Value Care NBP Cuffs and Philips Efficia Air Hoses 510(k) Summary

Prepared	September 18, 2015
Submission Type:	Special 510(k)
Regulatory Information	
Classification	Blood Pressure Cuff
Common/Usual name	Blood Pressure Cuff
Device trade name	Philips Value Care Philips Efficia
Proprietary Name	Value Care Cuff Large Adult Value Care Cuff Adult XL (extra long) Value Care Cuff Adult Value Care Cuff Small Adult Value Care Cuff Pediatric Value Care Cuff Infant Efficia Adult NIBP Air Hose, 3 M Efficia Adult NIBP Air Hose, 1.5 M
Model (same as reference number) (respectively to the above models)	989803160861 989803160851 989803160841 989803160831 989803160821 989803160811 989803160891 989803160881
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,  
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Device Classification:

The product code and individual classification monograph applicable to the subject devices is listed below

Device Panel	Classification	ProCode	Description
Cardiovascular	870.1120, II	DXQ	Blood Pressure Cuff

Predicate Device

510(k)	Date	Device	Owner/ Manufacturer	Trade Name	Models
K071885	12/20/2007	Philips Series of Multi-Patient cuffs and Single Patient Cuffs	Philips Medical Systems	Easy Care	M4552B, M4553B, M4554B, M4555B, M4556B, M4557B, M4558B, M4559B, M4562B, M4563B, M4564B, M4565B, M4566B, M4567B, M4568B, M4569B

Device Description

The Value Care Cuffs are a reusable single hose NBP cuff with a non-removable bladder. The Efficia Air hoses are standard tubing with compatible connector for the Value Care cuffs. The initial release encompasses six cuffs (Large Adult, Adult Long, Adult, Small Adult, Pediatric, Infant) and two air hoses (1.5 m and 3.0 m). They have color-coded tubings to differentiate them from other brands of cuffs and allow for quick cuff size identification. The patient contacting cuffs material is polyurethane coated polyester. The air hose tubing is made of PVC.

Fundamental Scientific Technology:

The design of the subject cuffs is similar to that of the predicate devices, with the integrated bladder, single hose, hook and loop closure. There are differences in material but testing of the subject devices demonstrates the same level of performance. The subject cuffs with subject air hoses demonstrated compliance with the requirements of the standards ANSI/AAMI/IEC 80601-2-30 and ANSI/AAMI/IEC 81060-1 as applicable to cuffs. The cuffs are for automated NBP devices. The fundamental scientific technology employed for the design of the subject Value Care NBP Cuffs and Efficia Air Hoses is the same as the predicate NBP cuffs and air hoses.

The performance testing completed demonstrates that the subject devices have the same level of safety and effectiveness as their predicate devices. The Value Care cuffs with Efficia air hoses demonstrate substantial equivalence as the Philips Easy Care family of cuffs cleared with K071885.

Indications for Use

Philips multi-patient and single-patient cuffs are intended for use by, or under the supervision of, a licensed physician or

other healthcare provider for the non-invasive measurement of infant, pediatric, and adult human blood pressure.

Philips air hoses are intended for use by, or under the supervision of, a licensed physician or other healthcare provider for the noninvasive measurement of neonatal, pediatric, and adult human blood pressure.

Conclusion

The subject Value Care Cuffs with Efficia Air hoses demonstrate the same level of performance as the predicate devices as determined from the results of the performance testing. The results support that the subject devices should perform to the same level of safety as the predicate devices.