



# PHILIPS

## Philips Medical Systems

Philips Medical Systems Nederland B.V. - P.O. Box. 10000 - 5680 DA Best, The Netherlands

5-18-92

Department of Health and Human Services  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Pre-Market Notification section.

ald. dept./ref. no.

Quality Assurance Dpt. XSB/XCB  
XB030-920159/RR/wp

onderw. re.

doorkiesnummer in-dialling

datum, date

1992.03.03

K921255

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION  
for

PHILIPS BV 26 system

The undersigned certifies that the 510(k) Pre-Market notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence.

This information and data is summarized as follows:

1. The BV 26 system is subject to Federal performance standards, defined in 21 CFR - part 1000;
2. The BV 26 system will be manufactured in accordance with the voluntary standards, listed in the enclosed External Standards survey;
3. The information for Users contains comprehensive information to insure safe and effective use;
4. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed in the Information for Users.

Ing. R.W. Rijntjes  
Approbation officer  
Quality Assurance dept. XSB / XCB  
Philips Medical Systems Nederland BV  
Best, The Netherlands.

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NOV 21 2011

Mr. William G. McMahon  
Manager of Regulatory Compliance  
Philips Medical Systems  
710 Bridgeport Avenue  
SHELTON CT 06484

Re: K921255

Trade/Device Name: BV-26 Mobile C-Arm Stand  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified Fluoroscopic x-ray system  
Regulatory Class: II  
Product Code: OXO  
Dated: March 13, 1992  
Received: March 16, 1992

Dear Mr. McMahon:

This letter corrects our substantially equivalent letter of May 18, 1992.

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 (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 contact 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Mary S. Pastel, Sc.D.  
Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure