K953910 **PHILIPS**

Philips Medical Systems

P.O. Box 10000, 5680 DA Best, Eindhoven, The Netherlands

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

Quality Assurance Dpt. XSB/XCB
XB030-950799/RR/wp

1995.07.04

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for

PHLIPS BV300 SERIES, MOBILE C-ARM SYSTEMS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990

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 BV300 Series, MOBILE C-ARM SYSTEM is subject to Federal performance standards, defined in 21CFR - part 1000;

2. The BV 300 Series, MOBILE C-ARM SYSTEM will be manufactured in accordance with voluntary safety standards, such as UL 187;

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
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
SHELTON CT 06484-4708

NOV 21 [illegible]

Re: K953910
Trade/Device Name: Philips BV 300 Series
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: August 18, 1995
Received: August 21, 1995

Dear Mr. Altman:

This letter corrects our substantially equivalent letter of October 18, 1995.

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,

for

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