SEP 2 1998

K982706

Philips Medical Systems

510(k) Summary

Company name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue, Shelton, CT 06484
Contact person:	Peter Altman
Telephone number:	203-926-7031
Prepared:	July 29, 1998
Device name:	Philips BV300 Series Release 2.1
Classification name:	Mobile X-Ray System
Common/Usual name:	Mobile C-Arm Fluoroscopic System
Predicate Device(s):	Philips BV300 Series (Release 1)

Intended use:

The Philips BV300 Series Release 2.1 systems are intended for surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the Operating Room.

System description:

The Philips BV300 Series Release 2.1 is a Mobile C-Arm X-Ray System offering Radiographic and Fluoroscopic techniques in a wide variety of applications. It has been designed primarily for use in the operating theater. All BV300 systems consist of a mobile C-arm stand with image intensifier and X-Ray unit, and a mobile View station with image processor, monitors and optionally archiving devices.

Substantial equivalence Information

The BV300 Series Release 2.1 is a modification of, and substantially equivalent to, the BV300 Series Release 1, 510(k) No. K953910.

Safety Information

The BV300 Series Release 2.1 complies with the applicable portions of 21 CFR parts 1020.30/.31/.32 and voluntary safety standards, such as UL 2601. The Information for Users contains comprehensive information to insure safe and effective use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Peter Altman
Director of Regulatory Affairs
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Re: K982706
Trade/Device Name: Philips BV300 Series Release 2.1
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: August 3, 1998
Received: August 4, 1998

Dear Mr. Altman:

This letter corrects our substantially equivalent letter of September 2, 1998.

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

510(k) Number (if known): ~~Unknown~~ K982706

Device Name : **Philips BV 300 Series, Release 2.1**

Indications For Use :

The Philips BV 300 Series Release 2.1 systems are Mobile C-Arm X-Ray Systems offering Radiographic and Fluoroscopic techniques in a wide variety of applications. The series has been designed primarily for use in the operating theater.

The Philips BV300 Series Release 2.1 systems are intended for the same applications as the BV300 Series Release 1, i.e. surgical interventions needing X-ray imaging and/or guidance and interventions inside and outside the Operating Room.

This includes cerebral, thoracic, abdominal, peripheral, orthopedic and vascular procedures. The systems are also suited as a back-up for a fixed vascular X-ray system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982706

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109

(Optional Format 1-2-96)