NOV 2 1998

PHILIPS

Philips Medical Systems

510(k) Summary

K983069

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:	August 31, 1998
Device name:	Philips DUO DIAGNOST
Classification name:	Fluoroscopic X-Ray System, 90JAA, 21 CFR 892.1680
Common/Usual name:	Remote-controlled Radiographic/Fluoroscopic System
Predicate Device(s):	Philips Diagnost 96

Intended use:

The Philips DUO DIAGNOST is a multi-functional diagnostic X-Ray system intended for Fluoroscopic, Radiographic, Angiographic, and Interventional applications.

System description:

The Philips DUO DIAGNOST is a remote controlled multi-functional R/F system consisting of a floor-mounted tilting patient support table and an undertable spotfilm device holding an image intensifier and the TV camera. The overtable X-Ray tube is supported by a combined floor/wall-stand. The X-Ray tube can be mechanically coupled to the table for fluoroscopy or spot film work and Radiography is possible in the coupled or uncoupled mode. The system comes with an X-Ray generator, trimode Image Intensifier, XTV imaging system, Philips glass or metal X-Ray tube, and TV monitor(s). An optional multiformat camera (PMI 100) can also be added, as can a **wallbucky stand**, and digital spot film camera.

Substantial equivalence Information

The DUO DIAGNOST is substantially equivalent to the Philips Diagnost 96 system (FDA ref. K912470).

Safety Information

This device complies with the federal X-Ray performance standards (CFR 1020.30, .31, .32) as well as with the relevant national and international standards for Electrical and Mechanical Safety (UL 2601-1, IEC 60601-1, IEC 60601-2-7, IEC 60601-2-32). 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

Mr. Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
710 Bridgeport Avenue
SHELTON CT 06484

AUG 23 2013

Re: K983069
Trade/Device Name: Philips DUO Diagnostic R/F Table
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: September 1, 1998
Received: September 2, 1998

Dear Mr. Altman:

This letter corrects our substantially equivalent letter of November 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 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting 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~~ K983069

Device Name : **Philips DUO DIAGNOST**

Indications For Use :

The Philips DUO DIAGNOST is a diagnostic imaging device intended for radiographic, fluoroscopic, angiographic, and interventional applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983069

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

(Optional Format 1-2-96)