PHILIPS

K961374

Philips Medical Systems

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

APR 19 [redacted]

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

. Qual. Ass. Dpt. XSB/XCB
XB030-960317/RR/gd

1996.03.01

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

for

PHILIPS MULTI DIAGNOST 4, UNIVERSAL TILT C-ARM SYSTEM

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 Multi Diagnost 4 system subject to Federal Performance Standards, defined in 21CFR - part 1000;

2. The Multi Diagnost 4 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, Inc.
North America Company
710 Bridgeport Avenue
SHELTON CT 06484

FEB 19 2013

Re: K961374
Trade/Device Name: PHILIPS MultiDIAGNOST 4
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: May 22, 1996
Received: May 23, 1996

Dear Mr. Altman:

This letter corrects our substantially equivalent letter of August 19, 1996.

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

Device Name : Philips MultiDIAGNOST 4

Indications For Use :

The MultiDIAGNOST 4 is indicated for use in Radiographic/Fluoroscopic, Angiographic, and Interventional diagnostic imaging examinations.

(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 K961374

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

(Optional Format 1-2-96)