MAY 13 2003

K031333

Philips Medical Systems

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O. Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person:	Lynn Harmer
Telephone No.:	(425) 487-7312
Date Prepared:	April 16, 2003
Device (Trade) Name:	Philips Integris Allura Flat Detector release 1.2 system
Classification Name:	Angiographic x-ray system, Class II, 90 IZI Solid x-ray Imager, Class II, 90 MBQ

Predicate Device:
The Philips Integris Allura Flat Detector release 1.2 system is substantially equivalent to the Philips Integris Allura Flat Detector release 1.0 system manufactured by Philips Medical Systems and GE Innova 4100 system. The Philips Integris Allura Flat Detector release 1.0 system received a 510(k) substantially equivalent determination in K022899 on November 22, 2002. The solid state x-ray Imaging device is the same product in both of the Integris Allura systems.

Device description:
The Philips Integris Allura Flat Detector release 1.2 system is an angiographic x-ray system with a solid state x-ray imaging device for cardiovascular and vascular diagnostic and interventional procedures. The monoplane system can be configured either a floor or ceiling suspended G-arm frontal stand. The x-ray detector is comprised of amorphous silicon with a cesium iodide scintilator. The system supports generating and recording x-ray diagnostic images using fluoroscopic and fluorographic techniques.

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X-ray images are detected with a flat dynamic x-ray detector and are recorded on digital storage medium. The system offers the functionality to review and analyze the images.

Digital images with corresponding patient and examination data may be archived on digital storage media, video or laser hardcopy.

Indications for Use:
The Philips Integris Allura Flat Detector release 1.2 system is intended for use in cardiovascular and vascular x-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology.

General Safety and Effectiveness:
The device and the labeling will comply with the applicable requirements of 21CFR, Subchapter J - Radiological Health, parts 1020.30, 32 and 1040.10
The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety UL 2601-1 and be classified by Underwriters Laboratories. The Philips Integris Allura Flat Detector release 1.2 system will also comply with the ACR/NEMA DICOM digital imaging communication standard.

Conclusion:
The Philips Integris Allura Flat Detector release 1.2 system is substantially equivalent in safety and effectiveness to the predicate devices identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2003

Philips Medical Systems
North America Company
% Mr. Morten S. Christensen
Senior Project Engineer
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050

Re: K031333
Trade/Device Name: Philips Integris Allura Flat Detector release 1.2
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulation Class: II
Product Code: 90 IZI
Dated: April 23, 2003
Received: April 28, 2003

Dear Mr. Christensen:

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 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031333

Indications for Use statement

510(k) Number (if known):

Device Name: Philips Integris Allura Flat Detector release 1.2

Indications for Use:

The Philips Integris Allura Flat Detector release 1.2 system is intended for use in cardiovascular and vascular x-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031333

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