K042334

SEP 27 2004

510(k) SUMMARY

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

Company Name: Address:	Philips Medical Systems North America Company 22100 Bothell Everett Highway P.O.Box 3003 Bothell, WA 98041-3003, USA
Registration No.:	1217116
Contact Person: Telephone No.:	Lynn Harmer (425) 487-7312
Date prepared:	11 August 2004
Device (Trade) Name:	Allura 3D-CA, release 1
Regulation Name:	Picture archiving and communications system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	90 LLZ

Predicate Device:
The Allura 3D-CA release 1 device is substantially equivalent to the Integris 3D-RA release 4.2. (FDA ref. K040254)

Device Description:
The Allura 3D-CA release 1 device contains an image processing computer loaded with 3D-CA application software. It is linked through a DICOM port to a Philips Cardio-Vascular X-ray system and is intended to be placed in the control room of the Angiographic suite. 3D Coronary Angiography refers to 3D scanning of the coronary arteries, employing a C-arm based X-ray system. 2D projections are generated during a rotational scan, in which the patient's heart is scanned over an angular range of ca. 100-120 degrees. The complexity of making a 3D image of the coronary arteries is mainly caused by motion of the heart. 3D-CA uses a cardiac modeling technique to obtain a still 3D model of the heart. Cardiac modeling allows the construction of a 3D surface model of a coronary segment, or multiple segments, from two 2D projection images.

Indications for Use:
The Allura 3D-CA release 1 device is intended to assist physicians when analyzing 2-Dimensional X-ray images by creating 3-Dimensional views from a pair of 2-Dimensional images created during rotational angiographic runs.

General Safety and Effectiveness:
The device and its labeling will comply with the applicable requirements of the federal performance standards (Code of Federal Regulations, Title 21, subchapter J – Radiological Health, parts 1020.10 and 1040.10). Additionally, the Allura 3D-CA release 1 complies with the ACR/NEMA DICOM digital imaging communication standard.

The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety - UL 60950. All required documents and reports have been or will be supplied to the appropriate oversight agency to establish compliance with the applicable requirements.

Conclusion:
The Allura 3D-CA release 1 does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Philips Allura 3D-CA release 1 substantially equivalent with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2004

Philips Medical Systems
North America Company
% Mr. Marc Mouser
Senior Project Engineer/Program Reviewer
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

Re: K042334
Trade/Device Name: Allura 3D-CA Release 1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: 90 LLZ and IZI
Dated: September 16, 2004
Received: September 17, 2004

Dear Mr. Mouser:

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 such 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

K042334

510(k) Number (if known) :

Device Name : **Allura 3D-CA release 1**

Indications For Use :

The Allura 3D-CA release 1 is intended to assist physicians when analyzing 2-Dimensional X-ray images by creating 3-Dimensional views from a pair of 2-Dimensional images created during rotational angiographic runs.

Prescription Use: **X** OR Over-The-Counter Use ....
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Lyttman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042334

(Optional Format 1-2-96)