DEC 21 1998

PHILIPS

510(k) Summary

Philips Medical Systems

K983877

Company name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue, Shelton, CT 06484
Contact person:	P. Altman
Telephone number:	203-926-7031
Prepared:	October 30, 1998
Device name:	**Philips Integris 3D RA Option**
Classification name:	Angiographic X-ray system, 21 CFR 892.1600 Class II (90 IZI)
Common/Usual name:	Angiographic x-ray system
Predicate Device(s):	Advantx LCN+ and LCLP+ (K974367).

Intended use:

The **Integris 3D RA Option** is intended to assist physicians when analyzing two dimensional, DSA X-ray images by creating three dimensional views from sets of two dimensional images created during Rotational angiographic runs.

System description:

The **Integris 3D-RA option** is comprised of an image processing computer loaded with 3D-RA software. It is linked through a DICOM port to the Integris system and is intended to be placed in the control room of the Angiography suite. The set of 2-Dimensional images from the rotational angiographic examination are transferred via DICOM Connection to the 3D RA Workstation. A 3-Dimensional image is reconstructed from the delivered image information resulting in an object which can be viewed from almnost any angle.

Substantial equivalence Information

The **Integris 3D RA Option** is substantially equivalent to the 3D image reconstruction and image intensifier distortion correction capabilities of the GE Medical Sytems' Advantx LCN+ and LCLP+ (K974367). Differences between the new and predicate device are identified in a Comparison matrix.

Conclusion:

It is the opinion of Philips Medical Systems that **Integris 3D-RA** is safe and potential hazards are controlled by a risk management plan including hazard analysis, system software quality assessment plan, software validation statement, test activities and external evaluations by hospitals. The use of Integris 3D-RA option does not change the intended use of the angiographic systems with which it is used.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1998

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
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Shelton, Connecticut 06484-0917

Re: K983877
Philips/Integris 3D RA Option for Angiographic X-Ray System
Dated: October 30, 1998
Received: November 2, 1998
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ K983877

Device Name : **Philips Integris 3D RA Option**

Indications For Use :

The 3D RA Option is intended to assist physicians when analyzing two dimensional, DSA X-ray images by creating three dimensional views from sets of two dimensional images created during Rotational angiographic runs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983877

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

(Optional Format 1-2-96)