FEB 4 2000

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Philips Medical Systems

510(K) Summary

K994210

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a 510(K) summary of safety and effectiveness for the following device.

SUBMITTER NAME / ADDRESS: Philips Medical Systems North America Company
710 Bridgeport Avenue
Shelton, CT 06484-0917

CONTACT PERSON / TEL NO: Frank Gianelli
Tel No: (203) 926-7729

DATE SUMMARY PREPARED: December 8, 1999

ESTABLISHMENT NO.: 1217116

TRADE/PROPRIETARY NAME: **Inturis Suite**

COMMON/USUAL NAME: Image Review Software for Angiographic X-ray System

CLASSIFICATION NAME: Angiographic X-ray System
(21 CFR 892.1600; Class II; Tier 2; 90-IZI)

PREDICATE DEVICE(S): ImageView Coronary Angiography Display and Review System; Heartware, Inc.

DEVICE DESCRIPTION:

Philips **Inturis Suite** is software comprised of modular software programs designed to perform the necessary functions required for the import, storage, archive, review, analysis, reporting and database management of digital cardiovascular angiographic images in DICOM 3.0 formats within and beyond the Cath Lab domain. **Inturis Suite** allows multiple users to quickly access and transfer multiple angiographic exams. **Inturis Suite** software can be installed and run on Windows NT based personnel computers for small applications and on UNIX based servers for high performance applications. The modular software design of **Inturis Suite**, allows users to tailor their image archive, transfer and communication requirements based on their particular performance needs and the number of cath labs importing images to an **Inturis Suite** via DICOM. **Inturis Suite** software will be provided on a CD-Rom which contains the installation program, the applicable executable files, DLL files and a readme file.

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INTENDED USE:

Philips **Inturis Suite** is intended to be used for the display and reading of cardiac angiographic images stored on a compact disk (CD) or an image server. **Inturis Suite** also allows the user to change the appearance of the images and export selected frames to other programs for printing and further manipulation.

SUBSTANTIAL EQUIVALENCE INFORMATION:

Inturis Suite is considered comparable and substantially equivalent to the following predicate device which has been cleared for commercial distribution via its referenced 510(k) submission.

- Device: ImageView Coronary Angiography Display and Review System
  Manufacturer: HeartWare, Inc.
  510(k) No.: K972229

TECHNOLOGICAL CHARACTERISTICS:

Predicate Device: ImageView Coronary Angiography Display and Review System, HeartWare, Inc.

Comparison matrix of main features: Inturis Suite vs. predicate device

Feature	Philips **Inturis Suite**	HeartWare **ImageView**
Operating system	Windows NT; UNIX	Windows 95; Windows NT
Memory requirement	128 MB (minimum) 256 MB (maximum)	32 MB (minimum) 128 MB (maximum)
Image source	DICOM 3.0 SCU DICOM 3.0 (CD-rom)	DICOM 3.0 SCU DICOM 3.0 CD-rom)
Display rate	up to 30 frames per sec	up to 30 frames per sec
Multiple windows	Yes	Yes
Digital zoom	Yes	Yes
Window (contrast)	Yes	Yes
Level (brightness)	Yes	Yes
Annotation	Yes	Yes
Image export	bmp, jpg, avi	bmp, gif
Network access	Yes	Yes

SAFETY INFORMATION:

Inturis Suite introduces no new safety and efficacy issues other than those already identified with the predicate device. The results of the hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Frank Gianelli
Senior Regulatory Affairs Specialist
Philips Medical Systems
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P.O. Box 860
Shelton, CT 06484-0917

Re: K994210
Inturis Suite
Dated: December 8, 1999
Received: December 14, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Gianelli:

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): K994210

Device Name : Philips **Inturis Suite**

Indications For Use :

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(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 K994210

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)