DEC 21 1999

PHILIPS

Philips Medical Systems

K993227

510 (k) Summary

Company Name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue Shelton, CT 06484
Contact Person	Peter Altman
Telephone Number:	203-926-7031
Prepared (date):	September 23, 1999
Device Name:	Philips Inturis DICOM Recorder
Classification Name:	Image Processing System (90 LLZ)
Common/Usual Name	Workstation
Predicate Device	Philips CD-Medical

System Description:

PHILIPS Inturis DICOM Recorder is software that can be loaded on a Personal Computer or workstation with a Windows NT (4.0) Operating System.

Intended Use:

The PHILIPS Inturis DICOM Recorder is intended for use in recording cardio-vascular images produced in the examination room (from the INTEGRIS systems, Easy Vision 4.3 onwards or 3D workstation), on a CD-R.

Safety Information:

No new hazards are introduced by the recording of patient/image information on CD disks.

Substantial Equivalence:

The PHILIPS Inturis DICOM Recorder is substantially equivalent to the Philips CD-Medical Recorder, K945460.

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
Fax: (203) 929-6099

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems, Inc.
710 Bridgeport Avenue
Shelton, Connecticut 06484-0917

RE: K993227
Philips Inturis DICOM Recorder Workstation
Dated: September 23, 1999
Received: September 27, 1999
Regulatory Class: II
21 CFR 892.2050/ Procode: 90 LLZ

Dear Mr. Altman:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The Federal Register notice exempting your device type was published on January 21, 1998, Vol. 63, No. 13, page 3142, and was effective immediately. Therefore, manufacturers of devices falling within the above classification regulation are now exempt from the premarket notification requirements of the Act if they comply with the classification criteria. Your device's product code, classification regulation and regulatory class are shown above. When listing your device with the Food and Drug Administration, please use this product code. We suggest that you review this above referenced regulation since it may grant other exemptions from certain general controls of the Act.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review the section entitled "Limitations on Exemptions" in the above referenced Federal Register notice to determine whether or not your new device(s) meets the exemption criteria. This Federal Register notice may be accessed on the World Wide Web at "www.fda.gov/cdrh/modact/frclass2.html" or obtained by facsimile from the Division of Small Manufacturers Assistance's Facts On Demand at (800) 899-0381 or (301) 827-0111. The order number for this notice is #394.

If you have any questions regarding this letter, please contact the Premarket Notification Staff at (301) 594-1190 or the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

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

510(k) Number (if known): K993227

Device Name : **Philips Inturis DICOM Recorder**

Indications For Use:

The PHILIPS Inturis DICOM Recorder is intended for use in recording cardio-vascular images produced in the examination room (from the INTEGRIS systems, Easy Vision 4.3 onwards, or 3D workstation), on a CD-R.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993227

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

(Optional Format 1-2-96)