NOV 24 1998

PHILIPS

K982795

Philips Medical Systems

510(k) Summary of Safety and Effectiveness

Company Name:	Philips Medical Systems North America Company
Address:	710 Bridegeport Avenue Shelton, CT 06484
Contact Person:	Peter Altman
Telephone Number:	203-926-7031
Prepared (date):	June 15, 1998
Device Name:	Philips BuckyVision
Classification Name:	Stationary Diagnostic X-ray System using Digital Solid State X-ray Imaging Detector
Common/Usual Name:	General Purpose X-ray System
Predicate Device:	Philips bucky Diagnost / Screen Film System

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

The Philips BuckyVision System uses the new x-ray imaging technology (Solid State X-ray Imager, SSXI), that converts x-rays directly into electrical signals which can, after appropriate processing, be displayed on a crt-monitor for medical diagnosis or printed out on laser-imager.
The basis of the system is a standard Philips bucky Diagnost System with additional TRIXELL PIXIUM-4600 SSXI connected to a Philips Thoravision-like workstation for worklist-managment, image-processing, image-exporting, and printing.
The complete system includes additional subsystems and components, like X-ray-tube(s), X-ray-generator, collimator, and optionally, a wall bucky with SSXI.

Intended Use:

The Philips BuckyVision is intended for use in general radiographic examinations and applications wherever conventional screen-film systems may be used (excluding fluoroscopy, angiography, and mammography).

Substantial Equivalence Information:

The Philips BuckyVision is of comparable type and substantially equivalent to:

the Philips bucky Diagnost System with Radiographic Screen Film Systems,	510(k) Number :	K945287,
the Sterling Diagnostic Imaging Direct Radiography™ device:	510(k) Number :	K973206
and the Philips Thoravision	510(k) Number :	K931071.

Therefore the Philips BuckyVision system complies to the same or equivalent standards and has the same intended use as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
710 Bridgeport Avenue
P. O. Box 860
Shelton, Connecticut 06484-0917

Re: K982795
Philips Bucky Vision Family Comprising:
bucky Diagnost TH (+SSXI) with bucky Diagnost CS2:
bucky Diagnost TH (+SSXI) with bucky Diagnost CS4;
bucky Diagnost VT (+SSXI) with bucky Diagnost CS2; and
bucky Diagnost VT (+SSXI) with bucky Diagnost CS4.
Dated: November 12, 1998
Received: November 13, 1998
Regulatory class: II
21 CFR 892.1680/Procode: 90 MQB
21 CFR 892.1680/Prodode: 90 KPR

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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 at (301) 443-6597.

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
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**

Device Name : **Philips BuckyVision**

Indications For Use :

The Philips BuckyVision is intended for use in general radiographic examinations and applications wherever conventional screen-film systems may be used (excluding fluoroscopy angiography, and mammography).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982795/S1

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