

JUN 18 1998



K9 81657
PHILIPS

Philips Medical Systems

510 (k) Summary of Safety and Effectiveness

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): May 7, 1998

Device Name: Philips Thoravision

Classification Name: Stationary Diagnostic X-ray System
(90 KPR)

Common/Usual Name: General Purpose X-ray system

Predicate Device: Philips Thoravision

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

System Description:

The **Philips Thoravision** was submitted as a radiographic system dedicated to chest imaging in 1993. It is now recognized that the system can also be used equally well for examinations of other anatomical areas. This extension to other anatomical areas has required only minor adjustments to the system, primarily in providing APRs addressing those new anatomical areas. As such, the screen layout of the user interface display has changed somewhat. No change has been made to the hardware.

Intended Use:

The **Philips Thoravision** intended use is being extended from its original use (limited to chest examinations) to include radiographic examinations for all anatomical areas.

Substantial Equivalence Information:

This submission introduces an extension to the Thoravision submitted and cleared under 510(k) K931071. This extension provides the capability to use the Thoravision for all general purpose radiographic examinations in addition to the previously cleared chest examinations.

The **Philips Thoravision for extended applications** is only a minor modification of, and therefore substantially equivalent to, the **Philips Thoravision** Chest system manufactured by **Philips Medical Systems**. The Thoravision received 510(k) clearance September 15, 1994 (see 510(k) K931071).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981657
Philips Thoravision
Dated: May 8, 1998
Received: May 11, 1998
Regulatory class: II
21 CFR 892.1680/Procode: 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 (for the indications for use stated in the enclosure) 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 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,

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 Thoravision

Indications For Use :

The Philips Thoravision is intended for use in general radiographic applications wherever conventional screen-film systems may be used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Symon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981657

Prescription Use
(Per 21 CFR 801.109

OR

Over-The-Counter Use