K983140

Philips Medical Systems

510(K) Summary

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: Peter Altman, Director of Regulatory Affairs
Tel No. (203) 926-7031

DATE SUMMARY PREPARED: September 4, 1998

ESTABLISHMENT NO.: 1217116

CLASSIFICATION NAME: Computed Tomography X-ray System
(21 CFR 892.1750; Class II; Tier 2; 90JAK)

COMMON/USUAL NAME: Option for CT X-ray System

TRADE/PROPRIETARY NAME: **CT BiopsyView**

PREDICATE DEVICE(S):
(1) Real-Time Reconstruction System option for Xpress/SX CT System; Toshiba America Medical Systems, Inc.
(2) C.A.R.E. Vision option to the SOMOTOM Plus 4 CT System; Siemens Medical Systems, Inc.

DEVICE DESCRIPTION:

CT BiopsyView is a software option to the Philips TOMOSCAN product family of computed tomography systems.

The TOMOSCAN products are whole body scanners. These systems are already provided with the RapidView Reconstructor (512 x 512 image matrix) option which allows the reconstruction of one image per second.

The CT BiopsyView option provides real-time CT fluoroscopy (6 images per second) for a TOMOSCAN CT system equipped with the RapidView reconstructor. The scan parameters are limited to 15, 25, 50 and 75 mA and 120 and 140 KV. The maximum exposure time is 100 seconds and the remaining time is displayed on the monitor for quick reference.

The CT BiopsyView option is used for interventional procedures, such as biopsy, drainage procedures, therapy control and functional studies.

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0860
Tel: 203 926 7674
Fax: 203 926 7098

INTENDED USE:

The CT BiopsyView option is intended to be used for instant display of CT images during interventional procedures. The instant display of images allows the operating physician to watch the placement of an interventional instrument in real-time.

CT BiopsyView is an option to the TOMOSCAN family of CT systems. TOMOSCAN systems are whole body Computed Tomography (CT) systems which are diagnostic X-ray systems intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission of data from the same axial plane taken at different angles. They includes signal analysis and display equipment, patient and equipment supports, component parts and accessories which are used in combination with signal and image processing software to facilitate the relative localization of anatomy with gray-scale representation of density relative to water utilizing Houndsfield indices with or without contrast mediums. They are used for the display, storage and analysis of digital diagnostic CT images. They are intended for use by a physician in the diagnosis and planning phases of patient conditions and treatment.

The CT BiopsyView option extends the intended use of a TOMOSCAN CT system to include its use by a physician in the interventional phases of patient conditions and treatment.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The CT BiopsyView option is considered comparable and substantially equivalent to the following predicate devices:

- Real-Time Reconstruction System option for the Toshiba Xpress/SX CT System (ref: K950972)
- C.A.R.E. Vision option to the Siemens SOMOTOM Plus 4 CT System (ref: K965004)

Each predicate device has been cleared for commercial distribution via its referenced 510(k) submission.

SAFETY INFORMATION:

The CT BiopsyView option introduces no new safety issues to the TOMOSCAN family of CT systems other then those already known with the TOMOSCAN system in which this option is used. Computed tomography is a mature technology with which industry and users have many years of experience. These devices must comply with the appropriate sections of the Radiation Control for Health and Safety Act. The CT BiopsyView option as part of the TOMOSCAN system and its associated labeling complies with the applicable requirements of the Federal X-ray Performance standards 21CFR 1020.30, 1020.33.

The Philips TOMOSCAN family of CT systems with which the CT BiopsyView option is used are designed to comply with the requirements of Underwriters Laboratories (UL) Standard for Safety of Medical Electrical Equipment (UL-2601) or UL Standard for Safety of X-ray Equipment (UL-187) and be classified by Underwriters Laboratories or an equivalent test laboratory. They are also designed to comply with the requirements of IEC601-1 (Medical Electrical Equipment).

The results of the hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the August 29, 1991 issue of the "Reviewer's Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 1998

Frank Gianelli
Senior of Regulatory Affairs Specialist
Philips Medical Systems
710 Bridgeport Avenue
Shelton, CT 06484

Re: K983140
BiopsyView CT Option
Dated: September 4, 1998
Received: September 8, 1998
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

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 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): K983140

Device Name : Philips **CT BiopsyView**

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 K983140

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

(Optional Format 1-2-96)