FEB 1 0 2003

K023785

Lung Nodule Assessment and Comparison Option

The following information is being supplied in accordance with 21CFR 807.92(a).

1. Submitter

Submitter: Philips Medical Systems (Cleveland), Inc.
595 Miner Road
Highland Heights, OH 44143
(440) 483-3000

Contact Robert L. Turocy
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
Highland Heights, OH 44143
Telephone: 440 483 3528
FAX: 440 483 2976

Date of Summary: November 6, 2002

2. Device Name

(Proprietary Name): Lung Nodule Assessment and Comparison Option

Classification Name: Computed Tomography X-Ray System

Common Name: Computed Tomography X-Ray System

The FDA has classified the Lung Nodule Assessment and Comparison Option as Class II in 21 CFR 892.1750 (Product Code 90JAK)

3. Intended Use

The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended to provide quantitative information about "physician-indicated" lung nodules that are identified on high-resolution computed tomography images of the lung.

The Lung Nodule Assessment and Comparison Option is used in a workstation (MxView) of a Computed Tomography X-Ray System intended to produce cross-sectional images of the lungs by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles

4. Predicate Device

In the opinion of Philips Medical Systems (Cleveland) Inc., the Lung Nodule Assessment and Comparison Option is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely the Image Processing Function on the Select CT/SP in CDRH Document Control No K961464 and K012009. See Appendix "G", Equivalent Device Comparison Matrix. This opinion is based on the fact that comparing the Image Processing Function on the Select CT/SP with the Lung Nodule Assessment and Comparison Option reveals that the devices comply with the same or equivalent standards and have the same or equivalent intended uses.

Functional specifications and operator's instructions (preliminary) are included in the Appendixes "B" and "C".

5. Safety and Effectiveness

Philips Medical Systems, Inc. adheres to FDA GMPs, 21 CFR 1020.30-33, and voluntary standards for safety/effectiveness (UL 2601) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and radiation). The Lung Nodule Assessment and Comparison Option is under the control of health care professionals who are trained and responsible for computed tomography examinations.

Philips has reviewed known information available and performed an investigation as to the causes of safety and effectiveness concerning the Lung Nodule Assessment and Comparison Option.

6. Substantial Equivalence Statement

The Lung Nodule Assessment and Comparison Option is substantially equivalent to legally marketed devices. The Lung Nodule Assessment and Comparison Option will be certified to comply with Federal Diagnostic X-Ray Performance Standards. Labeling (Product Specification and Operator's Manual) will be provided to the user of the equipment.

This opinion is based on the fact that comparing the Image Processing Function on the Select CT/SP and the Mx8000IDT to the Lung Nodule Assessment and Comparison Option reveals that the devices comply with the same or equivalent standards and have the same or equivalent intended uses.

The Lung Nodule Assessment and Comparison Option and the Image Processing Function on the Select CT/SP and Mx8000IDT CT Systems intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2003

Mr. Robert L. Turocy
Regulatory Affairs Manager
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K023785
Trade/Device Name: Lung Nodule Assessment and Comparison Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: November 6, 2002
Received: November 12, 2002

Dear Mr. Turocy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K023785** Page 1 of 1

Device Name: Lung Nodule Assessment and Comparison Option

Indications for Use: The Philips Medical Systems MxView Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended to provide quantitative information about physician-indicated lung nodules that are identified on high-resolution computed tomography images of the lung.

The Lung Nodule Assessment and Comparison Option is used in a workstation (MxView) of a Computed Tomography X-Ray System intended to produce cross-sectional images of the lungs by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023785