OCT - 1 2001

PHILIPS

Philips Medical Systems

K012238

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:	July 16, 2000
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:	**DoseRight**
PREDICATE DEVICE(S):	SmartScan option to the HiSpeed CT/I CT System; manufactured by GE Medical Systems

DEVICE DESCRIPTION:

DoseRight is a software option to the Philips CT Vision product family of computed tomography systems. The CT Vision products are whole body scanners. The CT Vision product family is comprised of the following systems. Each product has been cleared for commercial distribution via the referenced 510(k) submission.

- Philips CT Secura (previously named Tomoscan AV-NT, ref: K991278)
- Philips CT Secura MV (ref: K000819)
- Philips CT Aura (previously named Tomoscan CS, ref: K982631)

DoseRight is used to enable automatic dose regulation during scanning for the purpose of obtaining the desired image quality at the lowest possible dose. Using DoseRight, the dose required to attain a pre-determined image quality is calculated from the scanogram (scanned projection radiograph) of the patient and resultant scan parameters are then recommended to the user for the scan protocol. The user performs the scanogram in the normal way. At the completion of the scanogram, and with DoseRight enabled, a mAs/KV combination is displayed to the user, which is the recommended combination to use in the scan protocol to achieve a pre-determined user defined image quality relative to patient diameter. However, if the user so chooses, this recommendation can be ignored and the user can proceed with the standard protocol.

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INTENDED USE

DoseRight is intended to be used for automatic dose regulation during CT scanning for the purpose of obtaining the desired image quality at the lowest possible dose.

DoseRight is a software option to the CT Vision family of CT systems. These 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.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The DoseRight option is considered comparable and substantially equivalent to the following predicate device.

- SmartScan Option used in GE Medical System's HiSpeed CT/i CT System (ref: K964746)

The above-mentioned CT system has been cleared for commercial distribution via the referenced 510(k) submission.

SAFETY INFORMATION:

The DoseRight option introduces no new safety issues to the CT Vision family of CT systems other then those already known with these systems in which this type 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 DoseRight option as part of the CT Vision family of CT systems and its associated labeling complies with the applicable requirements of the Federal X-ray Performance standards 21CFR 1020.30, 1020.33.

The Philips CT Vision family of CT systems with which the DoseRight option is used are designed to comply with the requirements of Underwriters Laboratories (UL) Standard for Safety of Medical Electrical Equipment (UL-2601) and be classified by Underwriters Laboratories or an equivalent test laboratory. They are also designed to comply with the requirements of IEC 601-1 (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

OCT - 1 2001

Mr. Frank Gianelli
Senior Regulatory Affairs Specialist
Philips Medical Systems
North America
710 Bridgeport Avenue
P.O. Box 860
SHELTON CT 06484-0917

Re: K012238
Trade/Device Name: DoseRight Option for CT X-ray System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: 90 JAK
Dated: July 16, 2001
Received: July 17, 2001

Dear Mr. Gianelli:

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 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 this 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" (21 CFR Part 807.97). 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): K012238

Device Name : Philips **DoseRight**

Indications For Use :

DoseRight is intended to be used for automatic dose regulation during CT scanning for the purpose of obtaining the desired image quality at the lowest possible dose.

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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)

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

(Optional Format 1-2-96)

Mary C Broadon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012238