MAY 13 1999

PHILIPS

Philips Medical Systems

K991278

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.

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

COMMON/USUAL NAME: CT X-ray System

TRADE/PROPRIETARY NAME: Philips **Tomoscan AV-NT**

ESTABLISHMENT NO.: 1217116

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

DATE SUMMARY PREPARED: April 8, 1999

SYSTEM DESCRIPTION:

The Tomoscan AV-NT is a whole body scanner based on slipring technology. With the Tomoscan AV-NT, Philips introduces a new product to its Tomoscan product family which is based on and includes the technological features of existing computed tomography systems and support systems, i.e. Philips Tomoscan AV-E1, Tomoscan CS, and EasyVision Workstation.

The Tomoscan AV-NT is comprised of two main parts:

- The operator console (back-end part) to enable scanning and advanced image processing. It is comprised of a data acquisition part and a post-processing part with separate monitors and keyboards for each part.
- The gantry and patient table (front-end part). The gantry and table movements are controlled via the control panels on either side of the gantry. Patient positioning laser lights are mounted both externally on the gantry as an aid to patient positioning and at the scan plane.

All scanning facilities and features of the Tomoscan AV-NT are the same as with predicate devices Tomoscan AV-E1 (previously named Tomoscan SR8000, ref: K954255) and Tomoscan CS (ref: K982631). The viewing and image processing features of the predicate device EasyVision (ref: K920950) are integrated as part of the Tomoscan AV-NT system. The Tomoscan AV-NT can interface with selected PACS and RIS systems by using standard technology with UNIX based software and standard interfaces such as TCP/IP and DICOM 3. The Tomoscan AV-NT can be integrated with the Philips Inturis™ For Radiology information management products. The Tomoscan AV-NT can allow for the remote accessing of CT images via NetView which is an EasyVision integrated feature of the Tomoscan AV-NT. NetView allows authorized users to access images and reports via standard internet web browsers for non-diagnostic viewing on a PC or other computer.

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INTENDED USE:

The Tomoscan AV-NT is a whole body Computed Tomography (CT) system which is a diagnostic X-ray system 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. It 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. It is used for the display, storage and analysis of digital diagnostic CT images. The Tomoscan AV-NT is intended for use by a physician in the diagnosis and planning phases of patient conditions and treatment.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The Tomoscan AV-NT is considered substantially equivalent to the Philips Tomoscan AV-E1 (previously named Tomoscan SR8000, ref: K954255) and Tomoscan CS (ref: K982631) with respect to its scanning capabilities and it is considered substantially equivalent to the Philips EasyVision Workstation (ref: K920950) with respect to its viewing and post-processing features. Each predicate device has been cleared for commercial distribution via its referenced 510(k) submission.

SAFETY INFORMATION:

The Tomoscan AV-NT introduces no new safety issues to the TOMOSCAN family of CT systems other then those already known with the TOMOSCAN systems. These devices must comply with the appropriate sections of the Radiation Control for Health and Safety Act. The Philips Tomoscan AV-NT and its labeling complies with the applicable requirements of the Federal X-ray Performance standards 21CFR 1020.30, 1020.33. A Product Report according to 21 CFR 1002.10 will be submitted to FDA prior to the first delivery of the Tomoscan AV-NT. The Tomoscan AV-NT also complies with the international standard IEC-60601-1, national safety standard UL-2601-1 and the ACR/NEMA DICOM Version 3 digital imaging communication standard. The Tomoscan AV-NT is also Year 2000 compliant in accordance with the definitions set forth by the British Standards Institute committee BDD/1/-/3 in document DISC PD2000-1 ("A Definition of Year 2000 Conformity Requirements").

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 May 29, 1998 issue of "The Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAY 13 1999

Frank Gianelli
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Re: K991278
Philips Tomoscan AV-NT
Dated: April 9, 1999
Received: April 14, 1999
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K991278

Device Name: **Philips TOMOSCAN AV-NT**

Indications For Use:

The TOMOSCAN AV-NT is a whole body Computed Tomography (CT) system which is a diagnostic X-ray system 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. It includes signal analysis and display equipment, patient and equipment supports, component parts and accessories which 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. It is used for display , storage and analysis of digital diagnostic CT images. The TOMOSCAN AV-NT is intended for use by a physician in the diagnosis phases and planning phases of patient conditions and treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991278

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