

MAY 11 1998



K 980645
PHILIPS

Philips Medical Systems

XJR-148-3145/bf2
1998-02-16

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name : Philips Medical Systems North America Company.
Address : 710 Bridgeport Avenue
Shelton, CT 06484.
Registration No. : 1217116
Contact person : Peter Altman
Telephone Number : 203-926-7031
Prepared : February 16, 1998.

Device Name : **Philips Gyroscan NT Release 6 series.**
Classification Name : Magnetic Resonance Diagnostic Device.
Classification : Class II.
Performance standards : NEMA voluntary standards, FDA MRI guidances, UL and IEC 601 relevant safety standards and/or draft standards are used.
Common/Usual Name : Philips Gyroscan NT(*) Release 6 series.
Predicate Device(s) : Philips Gyroscan NT Release 5 series (FDA re.K963990).

Intended Use :

The Philips **Gyroscan NT Release 6 series** have the same intended use as its predecessor and predicate device Gyroscan NT Release 5. The Gyroscan NT systems are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ¹H and ³¹P metabolites, and that display the internal structure and/or function of the head, body or extremities. These images and/or spectra when interpreted by a trained physician, yield information that may assist in diagnosis.

Description :

The predicate device Gyroscan NT Release 5 series with the additions mentioned hereafter is called **Gyroscan NT Release 6 series.**

- The Synergy coils are based on the same principles of the existing Philips synergy coil but their physical design is as such for better matching with the ROI to be imaged.

Synergy Body coil: This coil consists of four coil elements to image the ROI in the abdomen and the pelvic or thoracic area.

Synergy Cardiac: This coil consists of 5 coil elements to image the heart and its coronary vessels

(*) By Gyroscan NT is meant all three versions, i.e. T5-NT (0.5T), T10-NT (1.0T) and ACS-NT (1.5T).



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- Contrast Enhanced Angiography (CE-MRA) Package - BolusTrak.

The BolusTrak package allows synchronization of a (3D FFE) Contrast Enhanced (CE) MRA scan with the arterial arrival of an intravenously injected contrast agent. After the administration of the contrast agent a rapid 2D FFE thick slice dynamic scan is started with real-time reconstruction, complex subtraction and viewing. At the moment the bolus is observed in the volume of interest a slower 3D FFE scan is started..

- Contrast Enhanced Peripheral Angiography Package - MobiTrak.

The MobiTrak package allows rapid evaluation of the aorta and lower extremity vasculature. It is an extension of contrast enhanced MRA, combining the advantages of 3D FFE CE acquisition with table movement between successive coronal acquisitions to overcome the limitation of a single field-of-view in relation to the large region-of-interest.

- **Respiratory Navigators (MotionTrak)** is an extension to the MR Cardiology package which offers the possibility to monitor the diaphragm position of the patient during scanning. Additional MR signals are acquired interleaved with the normal MR acquisition and evaluated in real-time. These navigator signals are used to determine the position of the imaging volume to enable gating and slice correction.

- **MR Neuro Imaging Package** provide dedicated acquisition, reconstruction techniques resulting in functional rather than anatomical information. It contains:

- o **MR Perfusion Package.** Enhanced 3D FFE and 3D FFE-EPI techniques , so-called PRESTO, which allows fast acquisition with large anatomical coverage. It provides high temporal information for evaluation of dynamic contrast agent studies.

- o **MR Bold Imaging Package.** Extensions to the PRESTO technique with respect to motion correction, acquisition and reconstruction, which offers the possibility of visualization of small susceptibility changes.

Introduction of Gyroscan CMR:

The dedicated cardiac version , based on the Gyroscan NT platform, will be marketed as Gyroscan CMR. The latter has the same performance as the NT version except for its appearance, i.e. the name and the color of the system covers.

Technological Characteristics:

The technological characteristics remain the same as those for other Gyroscan NT systems. New coils and sequences are available as the options are enabled.

General Safety and Effectiveness Concerns

The Philips GYROSCAN NT Release 6 series contains extensions to the Release 5 series which do not induce any other risks than the already known with MRI techniques.

Substantial Equivalence

The Philips GYROSCAN NT Release 6 series devices are substantially equivalent to the predicate devices of GYROSCAN NT Release 5 series.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, CT 06484-0917Re: K980645
Philips GYROSCAN NT Release 6 Series
Dated: February 18, 1998
Received: February 19, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

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 K980645
Device Name : Philips GYROSCAN NT Release 6 series

Indication 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)

David A. Seymour
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980645

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use