Summary of Safety and Effectiveness

MAY 29 1997

Philips GYROSCAN NT Systems

K963990

1. The GYROSCAN T5-NT (0.5T), GYROSCAN T10-NT (1.0T), GYROSCAN ACS-NT (1.5T) Release 5 series are designed and manufactured to comply with the relevant safety standards. Adequate safety precautions include RF-limit protection, rate of gradient change, and selection/decoupling circuitry for the applicable coils.

2. The systems, as their predecessors, are indicated for use as diagnostic devices producing transverse, sagittal, coronal, and oblique cross-sectional images and displaying the internal structure of the head, body, or extremities. These images, when interpreted by a trained physician, yield information useful in the determination of diagnosis.

3. MR Imaging utilizes mature technology to visualize images with which the industry and users have many years of experience. A Comprehensive Operator's Manual contains adequate instructions and provides sufficient cautions and warnings to ensure safe operation.

4. The software used in Release 5 is equivalent to the software used in the predicate device. The hardware used in Release 5 is identical to the predicte device.

Philips Medical Systems North America Company feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1997

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917

Re: K963990
GYROSCAN T5-NT, T10-NT and ACS-NT Release 5 Series
Dated: March 6, 1997
Received: March 7, 1997
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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/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**

Device Name : **Philips Gyroscan T5-NT, T10-NT, and ACS NT**

Indications For Use :

The **Philips 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 ^{1}H and ^{31}P 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.

(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 K963440

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

(Optional Format 1-2-96)