K992583

PHILIPS

OCT 18 1999

510(k) Summary

The following 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
Device (Trade) Name	:	Philips **Gyroscan INTERA** (*)
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH / LNI.
Performance standards	:	NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 601 appropriate safety standards and/or draft standards are used.
Common/Usual Name	:	Philips Gyroscan INTERA (Release 7 series).

Predicate Device(s).

The Philips cleared MRDD Philips GYROSCAN NT Release 6 series systems with FDA ref.K980645.

Intended use.

The **Philips Gyroscan INTERA (Release 7)** series have the same intended use as its predecessor and predicate device Gyroscan NT Release 6. The Gyroscan INTERA 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.

Device Description and Technological Characteristics

The new Philips MRDD being the successor of Gyroscan NT (Rel.6), is the **Release 7 series** called the **Gyroscan INTERA** series. The **Gyroscan INTERA** is based on the same platform as its predicate device Gyroscan NT (re.K980645) with the same technological characteristics and intended use .

(*)Gyroscan INTERA series are available in Gyroscan INTERA (0.5T), Gyroscan INTERA (1.0T), Gyroscan INTERA 1.5T (1.5T) and the CV version Gyroscan INTERA (1.5T)

The main enhanced and new feature of the **Gyroscan INTERA** series are:

- The new look in its appearance to emphasis its compactness.
- Hardware features to improve user friendliness such as the operator's console and the use of LCD monitor displays.
- Patients comfort by forced air flow through the magnet bore and comfort zone with Patient Observation provision. The patient can view the environment outside the bore and the built-in camera is used to observe the patient in the magnet bore.
- Save laser light cross beam is applied for reference for the patient positioning.
- A ceiling suspended Examination Room Operator's console with tracker-ball control and 20 inch LCD display.
- Enhanced and new functionality's :
  * RF receive only Synergy Pediatric Coil
  * The use of the XP1000 Compaq (Alpha processor) allowing image reconstruction up to 40 images/second.
  * Real-time Interactive Imaging.
  * On-line calculation of the ADC maps (Diffusion package)
  * On-line calculation of TTP, Negative Integral, Index, and MTT maps (Perfusion package).
  * Three-points Plan scan (enhancement Free Style Plan Scan).
  * Vector ECG signals for MR scan synchronization (triggering) and gating.

Safety parameters.

The safety parameters of the **Gyroscan INTERA** Release 7 remains the same as with its predecessor and predicate device Gyroscan NT Release 6 series (re. K980645).

General Safety and effectiveness.

The safety and effectiveness of the **Gyroscan INTERA** a re the same as with its predicate device the GYROSCAN NT Release 6 systems (ref.K980645)
It does not induce other safety issues and warnings than already valid for its predecessor and predicate device.

Substantial Equivalence.

The **Gyroscan INTERA** (Release 7 series) is substantially equivalent to the predicate device Philips GYROSCAN NT Release 6 series systems with FDA ref.K980645.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 1999

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

Re: K992533
Gyroscan Intera (Release 7 Series)
Dated: July 28, 1999
Received: July 29, 1999
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 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): ~~Unknown~~ K992533
Device Name : **Philips Gyroscan INTERA.**

Indication For Use :

The Philips **Gyroscan INTERA** (Release 7) series are indicated for use as magnetic resonance diagnostic devices (MRDD's) 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)

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

(Optional Format 1-2-96)

David A. Seltzer
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992533