K00 3516

PHILIPS

DEC 2 7 2000

Philips Medical Systems

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	:	**Gyroscan INTERA 3.0T.**
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH
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	:	**Gyroscan INTERA 3.0T.**

Predicate Device(s).

The **Gyroscan INTERA 3.0T** is an extension to the MRDD Philips Gyroscan INTERA family. The Gyroscan INTERA 3.0T is comparable to the Gyroscan INTERA 1.5T (510(k) number K001796) with the main difference being the high magnetic field. The Gyroscan INTERA 1.5T has a magnetic field strength of 1.5 Tesla and is a whole body scanner while the **Gyroscan INTERA 3.0T** has a magnetic field strength of 3.0 Tesla and is a head scanner only.

Intended Use.

The **Philips Gyroscan INTERA 3.0T** is a head scanner indicated for use as a diagnostic device that produces transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ^{1}H metabolites, and that displays the internal structure of the head. These images and/or spectra, when interpreted by a trained physician yield information that may assist in diagnosis.

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Device Description and Technological Characteristics

A. Device Description

The **Gyroscan INTERA 3.0T** is an extension to the Philips Gyroscan Intera family based on the same platform as its predicate device. The **Gyroscan INTERA 3.0T** has a magnetic field strength of 3.0Tesla and is a head scanner only

The main differences compared to the predicate device 1.5T version are:

- Magnetic field strength of 3.0 Tesla.
- T/R HEAD coil only.
- MR spectroscopy: Proton (H^1) only

The T/R Head is a transmit/receive Quadrature coil operating at 128 MHz, that is similar in design to the existing H^1 Spectroscopy Head coil of the other Gyroscan INTERA systems (1.5T). This coil is used for imaging as well as for H^1 spectroscopy. The **Gyroscan INTERA 3.0T** provides all imaging facilities as with the predicate device for head imaging applications. The software is the same as the predicate device, adapted to accommodate the field strength of 3.0 Tesla.

General Safety and Effectiveness.

The safety parameters of the **Gyroscan INTERA 3.0T** remain the same as with the FDA cleared Gyroscan INTERA (re. **K001796**).

The **Gyroscan INTERA 3.0T** does not introduce any new indications of use, nor does the use of this device result in any new potential hazard.

The **Gyroscan INTERA 3.0T** provides high resolution imaging and shorter acquisition times afforded by increased signal to noise.

Substantial Equivalence.

The **Gyroscan INTERA 3.0T** is substantially equivalent to its predicate device Gyroscan INTERA 1.5T and does not introduce any new indications of use, nor does the use of this device result in any new potential hazard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2000

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
Shelton, CT 06484

Re: K003516
GYROSCAN Intera 3.0T System
Dated: November 13, 2000
Received: November 14, 2000
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) 594-4639. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003516

Device Name : **Philips Gyroscan INTERA 3.0T.**

Indication For Use :

The **Philips Gyroscan INTERA 3.0T** is a head scanner indicated for use as a diagnostic device that produces transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ^{1}H metabolites, and that displays the internal structure of the head. 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 K003516

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

(Optional Format 1-2-96)