K973658

Philips Medical Systems Nederland B.V.

XJR-148-2985/bf
1997-09-09

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	:	September 9th, 1997.
Device Name	:	(Extended) DIFFUSION Package / GYROSCAN NT.
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	:	Diffusion Weighted MR Imaging.
Predicate Device(s)	:	- Spin Echo (SE) and Spin Echo Echo Planar (SE-EPI) imaging Philips GYROSCAN NT systems (FDA re. K963990). - SIEMENS Diffusion Weighted MRI / MAGNETOM Vision (FDA re.K971055).

Intended Use :
The (Extended) DIFFUSION Package provides the facility of Diffusion Weighted Imaging (DWI) which generates unique contrast/information about the diffusive mobility of water or other proton containing molecules. Change of the diffuse mobility of water or other proton containing molecules of tissue can be seen in a much earlier phase than originally possible with conventional proton density, T1 or T2 weighted imaging. This change indicates neurological anomalies of which diagnosis of acute stroke is one of the important application.

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System Description :
Sensitivity to diffusion has been induced by applying two identical large magnetic field gradient pulses, so-called diffusion gradients, to the basic (SE or SE-EPI) pulse sequences.
One diffusion gradient is applied before the 180 degree refocussing RF pulse and the second after the 180 degree RF pulse. During imaging static spins will be dephased as a result of the first applied diffusion gradient followed by complete rephasing by the second gradient pulse. If the molecules are moving in-between the two diffusion gradients, non-complete rephasing will occur, resulting in the diffusion weighting. Diffusion Weighted Imaging (DWI) on the Philips Gyroscan NT systems is offered in the following two optional packages:

- Diffusion package: allowing basic DWI sequences, based on Spin Echo (SE) sequences in combination with motion reduction techniques.
- Extended Diffusion Package: allowing faster acquisition as DWI is based on Spin Echo Echo Planar Imaging (SE-EPI) sequences with motion reduction techniques. Both Single Shot Diffusion EPI as well as multi-shot Diffusion EPI versions are possible.

Technological Characteristics:
The technological characteristics remain the same as those for other Gyroscan NT systems. New sequences are available as the option is enabled.

General Safety and Effectiveness Concerns
The new Diffusion Weighted MRI sequences are extensions to the already available Spin Echo (SE), Inversion Recovery (IR) and Spin Echo Echo Planar Imaging (SE-EPI) sequences.
Diffusion Weighted Imaging does not induce any other safety risks than the forementioned regular imaging techniques. No other warnings than those already valid for the above mentioned techniques are added to the Operator Manual of Gyroscan NT systems.

Substantial Equivalence
The (Extended) DIFFUSION package is substantially equivalent to the commercially available Gyroscan NT sequences like SE, IR and SE-EPI and the Siemens Diffusion Weighted - MR Imaging.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 6 1998

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

Re: K973658
MRI Sequence (Diffusion Imaging Package for
Philips Gyroscan NT MR Systems
Dated: February 2, 1998
Received: February 5, 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~~ K973658

Device Name : **DIFFUSION and Extended DIFFUSION Package for PhilipsGyroscan NT**

Indications For Use :

Diffusion Weighted Imaging is intended for use in generating unique contrast/information about the diffuse mobility of water or other proton containing molecules. Changes in mobility of the apparent diffusion coefficients in tissue can be seen much earlier phase than originally possible with conventional proton density, T1 or T2 weighted imaging. This change indicates neurological anomalies, of which diagnosis of acute stroke is one of the important applications.
Diffusion Weighted Imaging generates contrast/information about the apparent diffusion coefficients that reflect the anisotropic nature of tissue composition (e.g. fiber tracts in brain white matter) that otherwise cannot be visualized by conventional proton density, T1 or T2 weighted imaging.

(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 ~~K98~~ K973658

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

(Optional Format 1-2-96)