K052078

SEP - 7 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

General information

Company Name:	Philips Medical Systems Nederland BV Attn: Budhy Fredriksz, MR Q & RA
Address:	Veenpluis 4-6 5684 PC Best, Netherlands,
Registration No.:	300376277
Contact person:	Lynn Harmer Manager, Regulatory Submissions Tel: (425) 487-7312 Fax: (425) 487-8666 Lynn.Harmer@Philips.com
Date Prepared:	26 July 2005
Device (Trade) Name:	**ACHIEVA , INTERA and PANORAMA 1.0T.**
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Regulatory Number:	892.1000
Classification:	Class II
Product code:	LNH
Performance standards:	NEMA voluntary standards, FDA MR Diagnostic Device Guidance, UL and IEC 60601 appropriate safety standards and/or draft standards are used.

Predicate Device(s):

The **ACHIEVA , INTERA and PANORAMA 1.0T Release 2-series** are the successor of the predicate devices ACHIEVA, INTERA and PANORAMA 1.0T release 1-series. (FDA references K043147, K043147 & K041602).

Indications for use:

The **ACHIEVA , INTERA and PANORAMA 1.0T Release 2-series** are magnetic resonance diagnostic devices that produce cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Device description:

The ACHIEVA , INTERA and PANORAMA 1.0T Release 2-series are the successor of the predicate devices ACHIEVA, INTERA and PANORAMA 1.0T release 1-series. The Release 2-series introduces the new functionalities:

- **Fiber Tracking**
  Diffusion Tensor Imaging (DTI) extends the functionality of Diffusion Weighted Imaging (DWI) to measure the directional dependence of the diffusion coefficient in tissue. With Fiber Tracking the directional dependency can be used to visualize the white matter structure in the brain.
- **Smart Scan**
  SmartScan enables automatic planning of geometries and acquisition. When needed the user can control and confirm the automatically planned acquisition. The ExamCard provides the fully automated process of data acquisition.
  Regional Perfusion Imaging (Arterial Spin Labeling)
  Regional Perfusion Imaging with Arterial Spin Labeling provides a noninvasive acquisition method for selectively mapping of the flow territories and to determine the regional perfusion in the human brain.
- **kt-BLAST and kt-SENSE.**
  Kt-BLAST (Broad-use Linear Acquisition Speed-up Technique) reduces scan time of dynamic and multi-phase studies by also using k-space data from other dynamics / phases. Kt-SENSE combines kt-BLAST with SENSE parallel imaging. Kt-blast and kt-SENSE can be applied to reduce scan time or improve temporal resolution of dynamic or multi-phase studies.

The **ACHIEVA, INTERA and PANORAMA 1.0T Release 2-series** are the successors of the predicate devices ACHIEVA , INTERA and PANORAMA 1.0T Release 1-series. The design of the Release 2-series are based on the same software platform and hardware technology as their predicate devices.

General Safety and Effectiveness

The **ACHIEVA, INTERA and PANORAMA 1.0T Release 2-series** do not induce any other risks than already indicated for their predicate devices with the same safety and effectiveness.

Substantial Equivalence

It is the opinion of Philips Medical Systems that the Philips **ACHIEVA, INTERA and PANORAMA 1.0T Release 2-series** are substantially equivalent to their predicate devices Release 1-series.

End

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medical Systems Nederland BV
% Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems North America
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K052078
Trade/Device Name: Achieva, Intera & Panorama 1.0T Release 2-series
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 28, 2005
Received: August 1, 2005

Dear Ms. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K052078

Device Name : **ACHIEVA, INTERA & PANORAMA 1.0T Release 2-series.**

Indication For Use :

The **ACHIEVA , INTERA and PANORAMA 1.0T Release 2-series** are magnetic resonance diagnostic devices that produce cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052078