K063559

Appendix IVa

XJR148-7491

JAN - 4 2007

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
Address:	Veenpluis 4-6 5684 PC Best, Netherlands,
Registration No.:	3003768277
Contact person:	Lynn Harmer Manager, regulatory Submissions Tel: (425) 487-7312 Fax: (425) 487-8666 Lynn.Harmer@Philips.com
Date Prepared:	
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:	90L--NH 90L--NI
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 2.5-series** are the successor of the predicate devices ACHIEVA, INTERA and PANORAMA 1.0T release 2-series. (FDA references K043147, K041602, K052078 and K013344).

Indications for use:

The **ACHIEVA , INTERA and PANORAMA 1.0T Release 2.5-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.

In addition the Achieva, Intera and Panorama 1.0T devices provide capabilities to perform interventional procedures in the head, body and extremities, which may be facilitated by MR techniques, such as real time imaging. Such procedures must be performed with MR compatible instrumentation as selected and evaluated by the clinical user.

Device description:

The ACHIEVA , INTERA and PANORAMA 1.0T Release 2.5-series are the successor of the predicate devices ACHIEVA, INTERA and PANORAMA 1.0T release 2-series. The Release 2.5-series introduces the new functionalities:

- **Cardiac MR Functional Analysis**
  Cardiac MR Functional Analysis provides volumetric analysis of both left and right ventricle, and wall studies (motion, thickness and thickening).
  - Quick Area Length Analysis
  - Automatic slice-to-slice segmentation provides accurate and ultra-fast propagation of an initial user-drawn contour over all heart phases.
  - Papillary muscles may be identified and used as a corrective term for blood volume calculations.
  - User-defined spoke wheel allows results to be shown in terms of anatomically relevant areas.
  - Various numerical and graphical results are provided for optimal data interpretation.
- **4D-THRIVE**
  4D-THRIVE is an enhancement of the THRIVE package which combines THRIVE with 4D TRACKS. This is particularly useful for fast, dynamic 3D abdominal and breast studies. The aforementioned packages THRIVE and 4D TRACKS are FDA cleared via former submissions.
- **Prospective Motion Correction**
  Prospective Motion Correction (PMC) automatically accounts for subject motion by continually monitoring subject motion during the acquisition and modify the geometry parameters accordingly in real time. It will avoid registration in post-processing while improving overall registration accuracy.
  PMC is a feature of PRESTO Imaging and BOLD Imaging.
- **Propeller**
  Propeller eliminates the effects of patient and physiological motion through the combination of radial imaging and over sampling of data in order to be able to correct for patient and physiological motion. Applying PROPELLER with existing imaging methods (e.g. TSE or TFE) provides motion corrected images in general imaging and diffusion imaging.
- **CMR Prepulse Imaging**.
  The Prepulse Imaging package enables cardiac triggered multi-slice dynamic imaging in combination with prepulses for image contrast manipulation. Prepulse Imaging may provide a powerful tool complementary to cardiac function studies. Cardiac MR Prepulse analysis provides analysis of cardiac triggered multi-slice dynamic images in combination with prepulses for image contrast manipulation.
- **CMR IR-TFE T1 Imaging**
  IR-TFE T1 Imaging can be used for cardiac-triggered T1 analysis of the myocardial tissue with full heart coverage.
  Cardiac MR IR-TFE T1 Imaging Assessment enables the quantitative evaluation of inversion recovery over time.

- **Cardiac MR Reporting**
  Cardiac MR Reporting provides a user-defined template to report the total cardiac MR case. All results obtained with the extended MR WorkSpace analysis packages are included the report.
- **Rapid Focus**
  Rapid Focus is a post-processing software package intended for use in viewing and analyzing dynamic magnetic resonance imaging (MRI) studies. Rapid Focus automatically registers serial patient image acquisitions (in 2D or 3D) to minimize the impact of patient motion, segments and labels tissue types based on enhancement characteristics (parametric image maps), and provides quantitative measurements of morphological features of the segmented tissues. Rapid Focus performs other user-defined post-processing functions (image subtractions, multi-planar reformats, maximum intensity projections, image averaging, discarding areas containing motion artifacts).
  Rapid Focus also can be used to provide accurate and reproducible measurements of the segmented tissue volumes (volumes of interest - VOI). These measurements include longest diameter, longest in-plane diameters, volume measurement, ratio of breast volume to VOI, distance of VOI to anatomical landmarks, and 3D renderings of the VOI.
  The resulting information can be displayed in a variety of formats, including the parametric image maps as color overlays onto the source data. Rapid Focus can be used to display previous studies, including other modalities, such as ultrasound and X-ray images.
  Rapid Focus also includes the option to add annotations based on the American College of Radiology's Breast Imaging Reporting and Data System (BI-RADS) Breast Imaging Atlas.
- **Rapid Locus**
  Rapid Locus is a post-processing software package intended for use to support the use of interventional coils and MR stereo-tactic localization devices to perform MR-guided interventional procedures. Using information from MR images regarding the coordinates of a user-specified region of interest, and fiducial coordinates, the software provides an automatic calculation of the location and depth of the targeted region of interest, such as a lesion or suspected lesion.
- **Interventional procedures**
  The Achieva, Intera and Panorama 1.0T systems can be used for imaging during interventional procedures when performed with MR-compatible devices such as in-room display and MR-safe biopsy needles.
- **Achieva 3.0T mobile**
  As for Intera 1.5T and Achieva 1.5T systems it is also possible for Achieva 3.0T systems to built the system into a trailer.

The **ACHIEVA, INTERA and PANORAMA 1.0T Release 2.5-series** are the successors of the predicate devices ACHIEVA , INTERA and PANORAMA 1.0T Release 2-series. The design of the Release 2.5-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 2.5-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 2.5-series** are substantially equivalent to their predicate devices Release 2-series.

End

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Philips Medical Systems
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JAN - 4 2007

Re: K063559
Trade/Device Name: ACHIEVA, INTERA & PANORAMA 1.0T Release 2.5-series
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 18, 2006
Received: December 20, 2006

Dear Mr. Job:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

Appendix IVb

510(k) Number (if known): K063559

Device Name : **ACHIEVA, INTERA & PANORAMA 1.0T Release 2.5-series**

Indication For Use :

The **ACHIEVA , INTERA and PANORAMA 1.0T Release 2.5-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.
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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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063559