K110151
P1/2

Appendix 12

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 2 2 2011

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<br>5684 PC Best, Netherlands, |
| **Registration No.:** | 3003768277 |
| **Contact person:** | Lynn Harmer<br>Manager, Regulatory Affairs<br>Tel: (425) 487-7312<br>Fax: (425) 487-8666<br>Lynn.Harmer@Philips.com |
| **Date Prepared:** | December 8, 2010 |
| **Device (Trade) Name:** | **ACHIEVA R4 1.5T and ACHIEVA R4 3.0T (aka Ingenia)** |
| **Classification Name:** | Magnetic Resonance Diagnostic Device (MRDD) |
| **Regulatory Number:** | 892.1000 |
| **Classification:** | Class II |
| **Product code:** | 90L--NH<br>90L--NI<br>90M--OS |
| **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 R4 1.5T and ACHIEVA R4 3.0T with enhancements are the successors of their predicate devices ACHIEVA 1.5T and ACHIEVA 3.0T MR systems Release 2.5-series (FDA references K063559, K043147, K041602, K052078 and K013344.)

**Intended Use:**

The ACHIEVA R4 1.5T and ACHIEVA R4 3.0T 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 R4 1.5T and ACHIEVA R4 3.0T 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.

## 1 Device description:

The next generation Philips MR platform consists of either a 1.5T or 3.0T field generating superconducting unit. The radiofrequency receive chain consists of multiple coil types delivering a simplified and unique data acquisition system. The system is configured with a time-varying magnetic field system (gradients). Additional RF transmission is provided through an integrated RF body coil. The base software for the above mentioned system will be called Release 4.

The magnetic resonance diagnostic device is used to produce cross-sectional images, spectroscopic imaging and/or spectra in any orientation of the internal structures of the whole body. These images when interpreted by a trained physician, yield information that may assist in a diagnosis. In addition, the device provides the 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.

## 2 General Safety and Effectiveness

The ACHIEVA R4 1.5T and ACHIEVA R4 3.0T do not induce any other risks than already indicated for their predicate devices with the same safety and effectiveness.

## 3 Substantial Equivalence

It is the opinion of Philips Medical Systems that the Philips ACHIEVA R4 1.5T and ACHIEVA R4 3.0T are substantially equivalent to their predicate device ACHIEVA 1.5T and ACHIEVA 3.0T MR systems Release 2.5-series.

**510(k) Contrast Agent Use Form**

# K110151

| | |
|---|---|
| Date | Monday, March 21, 2011 |
| Reviewer | Jana Delfino |
| Sponsor | Philips Medical Systems Nederland BV |
| Device | Achieva R4 1.5T and Achieva R4 3.0T MR Systems |
| IFU | "The ACHIEVA R4 1.5T and ACHIEVA R4 3.0T 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.<br><br>In addition, the ACHIEVA R4 1.5T and ACHIEVA R4 3.0T devices provide capabilities to perform interventional procedure sin 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." |
| Imaging Agent Use | gadolinium-based contrast media |
| Was an outstanding drug issue letter sent after a previous submission? | No |

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Predicate Device:

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|---|---|
| 510(k) Number | K063559 |
| IFU | "The ACHIEVA, INTERA, and PANORMA 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 the diagnosis.<br><br>In addition, these 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." |
| Imaging Agent Use | any gadolinium-based contrast agent |

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Second Predicate (if applicable):

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|---|---|
| 510(k) Number | K043147 |
| IFU | "The ACHIEVA family consists of 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." |
| Imaging Agent Use | any gadolinium-based contrast agent |

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Third Predicate (if applicable):

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|---|---|
| 510(k) Number | |
| IFU | |
| Imaging Agent Use | t |

Fourth Predicate (if applicable):

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|---|---|
| 510(k) Number | |
| IFU | |
| Imaging Agent Use | |

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Lynn Harmer
Senior Manager, Regulatory Affairs
Philips Healthcare
22100 Bothell Everett Highway
BOTHELL, WASHINGTON 98021

MAR 2 2 2011

Re: K110151
Trade/Device Name: **Achieva R4 1.5T and Achieva R4 3.0T MR Systems**
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: January 14, 2011
Received: January 18, 2011

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**APPENDIX 10**

# Indication for use

510(k) Number (if known): K110151

Device Name : **ACHIEVA R4 1.5T and ACHIEVA R4 3.0T**

**Indication For Use** :

The **ACHIEVA R4 1.5T and ACHIEVA R4 3.0T** 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 R4 1.5T and ACHIEVA R4 3.0T 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.

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)

Mary S Pastel 22 Mar 11

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K