DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 22, 2016

Philips Medical Systems, Nederlands B.V.
% Mr. Henrie Daniels
Regulatory Affairs Engineer
Veenpluis 4-6
Best, 5684 PC
THE NETHERLANDS

Re: K153324
Trade/Device Name: Ingenia 1.5T and Ingenia 1.5T S R5.2
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI
Dated: February 16, 2016
Received: February 18, 2016

Dear Mr. Daniels:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153324

Device Name

Ingenia 1.5T and Ingenia 1.5T S R5.2

Indications for Use *(Describe)*

This system is a Magnetic Resonance Medical Electrical Systems indicated for use as a diagnostic device.

The system can produce cross-sectional images, spectroscopic images and/or spectra in any orientation of the internal structure of the head, body or extremities.

Magnetic Resonance images represent the spatial distribution of protons or other nuclei with spin. Image appearance is determined by many different physical properties of the tissue and the anatomy, and the MR scan technique applied. The image acquisition process can be synchronized with the patient's breathing or cardiac cycle. The systems can use combinations of images to produce physical parameters, and related derived images.

Images, spectra, and measurements of physical parameters, when interpreted by a trained physician, provide information that may assist the diagnosis and therapy planning. The accuracy of determined physical parameters depends on system and scan parameters, and must be controlled and validated by the clinical user. For some studies the use of contrast agents can be essential. Their application is subject to local medico-legal regulations and to their appropriateness to assist the diagnosis and therapy planning as judged by a trained physician.

In addition the Philips MR systems provide imaging capabilities, such as MR fluoroscopy, to guide and evaluate interventional and minimally invasive procedures in the head, body and extremities.

MR Interventional procedures, performed inside or adjacent to the Philips MR system, must be performed with MR Conditional or MR Safe instrumentation as selected and evaluated by the clinical user for use with the specific MR system configuration in the hospital. The appropriateness and use of information from a Philips MR system for a specific interventional procedure and specific MR system configuration must be validated by the clinical user.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	March 16, 2016	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6, 5684 PC, Best, The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person: **Secondary Contact Person**	Henrie Daniels Regulatory Affairs Engineer Phone: +31 40 2762192 E-mail: henrie.daniels@philips.com Ruojuan Zhang Regulatory Affairs engineer Phone: +31 631685825 E-mail: ruojuan.zhang@philips.com	
Device Name:	**Ingenia 1.5T and Ingenia 1.5T S R5.2**	
Classification:	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Regulation:	21CFR §892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product code:	90LNH 90LNI
Primary Predicate Device:	Trade Name:	ACHIEVA R4 1.5T and ACHIEVA R4 3.0T (aka Ingenia)
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K110151 (March 22, 2011)
	Classification Regulation:	21 CFR, Part 892.1000
	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	90LNH

		90LNI
Device description:	The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature is provided with a 70 cm magnet. ScanWise Implant functionality enables MR technologists to implement an improved and controlled workflow for MR Conditional implants. The feature consists of an extension to the Patient Registration User Interface where the information relevant to MR Conditional device labeling can be assessed, controlled and reviewed. The ScanWise Implant feature allows the user *at the examination level* to define restrictions on the 'active fields' generated by the MR system. The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature also consolidates separately-cleared novel functionalities, and minor hardware and software changes since the clearance of the currently marketed and predicate device, Ingenia R4 (K110151, 03/22/2011). Following minor hardware and software changes are covered in this submission: 1. (Hardware) Enhanced Patient Communication User Interface Module, IEC/ISO compliant symbols. 2. (Hardware) New computing platform and peripherals for MR Spectrometer (DDAS). 3. (Software) User Interface layout modifications for scan preparation, sequence planning (geometries and parameters), and data processing and viewing. 4. (Software) Planning on cine images. 5. (Software) SAR related parameters (SED). Pregnancy status related to Normal Mode. 6. (Software) Parameter optimization for the reconstruction algorithms. 7. (Software) Partial NSA algorithm in reconstruction. 8. (Software) AutoVoice, using pre-recorded spoken instructions. 9. (Software) VCG, optimized electrode placement and enhanced algorithm. 10. (Software) ComforTone: mechanical resonance frequency dependent timing adjustments of sequences for lower acoustic noise. 11. Enhanced sequences: a. AutoSpair. b. TSE flow compensation enhancement. c. Optimized 3D TSE flip angle sweeps per anatomy.	

	d. ENCASE: 3D encoding. e. CardiacQuant: triggered T1 mapping sequence. f. pCASL. g. DTI enhancements.
Indications for Use:	This system is a Magnetic Resonance Medical Electrical Systems indicated for use as a diagnostic device. The system can produce cross-sectional images, spectroscopic images and/or spectra in any orientation of the internal structure of the head, body or extremities. Magnetic Resonance images represent the spatial distribution of protons or other nuclei with spin. Image appearance is determined by many different physical properties of the tissue and the anatomy, and the MR scan technique applied. The image acquisition process can be synchronized with the patient's breathing or cardiac cycle. The systems can use combinations of images to produce physical parameters, and related derived images. Images, spectra, and measurements of physical parameters, when interpreted by a trained physician, provide information that may assist the diagnosis and therapy planning. The accuracy of determined physical parameters depends on system and scan parameters, and must be controlled and validated by the clinical user. For some studies the use of contrast agents can be essential. Their application is subject to local medico-legal regulations and to their appropriateness to assist the diagnosis and therapy planning as judged by a trained physician. In addition the Philips MR systems provide imaging capabilities, such as MR fluoroscopy, to guide and evaluate interventional and minimally invasive procedures in the head, body and extremities. MR Interventional procedures, performed inside or adjacent to the Philips MR system, must be performed with MR Conditional or MR Safe instrumentation as selected and evaluated by the clinical user for use with the specific MR system configuration in the hospital. The appropriateness and use of information from a Philips MR system for a specific interventional procedure and specific MR system configuration must be validated by the clinical user.
Fundamental Scientific Technology:	The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature is based on the principle that certain atomic nuclei present in the human body will emit a weak relaxation signal when placed in a strong magnetic field and excited by a radio signal at the precession frequency.

	The emitted relaxation signals are analyzed by the system and a computed image reconstruction is displayed on a video screen. The principal technological components (magnet, transmit body coil, gradient coil, receive coils and patient support) of the proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature is identical to those used in the currently marketed and predicate device, Ingenia R4(K110151, 03/22/2011). ScanWise Implant uses existing safety mechanisms to protect the patient against excessive RF exposures. This includes Whole Body and Head SAR, local SAR controls, and display of B1+rms. No modifications relative to the implementation of safety mechanisms relative to the predicate device was required. ScanWise Implant extends existing software safety provisions to prevent peripheral nerve stimulation. In previous products, dB/dt was evaluated (at the compliance volume defined in IEC60601-2-33) and displayed for informational purposes. In this software, dB/dt is controlled not to exceed a user-specified value. Based on the information provided above, the proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature does not raise different questions of safety and effectiveness compared to the marketed and predicate device, Ingenia R4(K110151,03/22/2011).
Summary of Non-Clinical Performance Data:	The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature comply with the following international and FDA-recognized consensus standards: • IEC60601-1 Edition 3 Amendment 1 • IEC60601-1-2 Edition 3 • IEC60601-1-6 Edition 3 / IEC62366 • IEC60601-1-8 Edition 2 • IEC60601-2-33 Edition 3 Amendment 1 • IEC 62304 • NEMA MS-1 2008 • NEMA MS-4 2008 • NEMA MS-8 2008 • ISO 14971 Application of risk management to medical devices (2007) • Device specific guidance document, entitled “Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 14, 1998”

	Non-Clinical verification and or validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results. Specifically for ScanWise Implant, Human Factors Engineering testing was performed in line with FDA's guidance document entitled "Applying Human Factors and Usability Engineering to Optimize Medical Device Design - June 22, 2011". The verification, validation test results and sample clinical images demonstrate that the proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature: • Complies with the aforementioned international and FDA-recognized consensus standards and Device specific guidance document, entitled "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 14, 1998" • Meets the acceptance criteria and is adequate for its intended use. Therefore, the proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature is substantially equivalent to the currently marketed and predicate device, Ingenia R4(K110151, 03/22/2011) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature did not require clinical study since substantial equivalence to the primary currently marketed and predicate device was demonstrated with the following attributes: • Design features; • Indication for use; • Fundamental scientific technology; • Non-clinical performance testing; and • Safety and effectiveness.
Substantial Equivalence Conclusion:	The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature and the currently marketed and predicate device, Ingenia R4(K110151, 03/22/2011) have the same primary indications for use with respect to the following: • Providing cross-sectional images based on the magnetic resonance phenomenon • Interpretation of the images is the responsibility of trained physicians • Images can be used for interventional and treatment planning purposes

	The proposed I**ngenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature and control software are substantially equivalent to the currently marketed and predicate device, Ingenia R4 (K110151, 03/22/2011) in terms of improving the user control of safety related parameters in MR Conditional workflows. The proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature are substantially equivalent to the currently marketed and predicate device, Ingenia R4,(K110151, 03/22/2011), in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards and device-specific guidance. The results of these tests demonstrate that the proposed **Ingenia 1.5T and Ingenia 1.5T S R5.2** with ScanWise Implant feature met the acceptance criteria and is adequate for its intended use.