



April 4, 2018

Philips Medical Systems Nederland B.V.  
% Susan Quick  
Regulatory Affairs  
Philips Medical Systems (Cleveland) Inc  
595 Miner Road  
Cleveland, Ohio 44143

Re: K173079

Trade/Device Name: Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T  
CX R5.4

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: Class II

Product Code: LNH, LNI

Dated: March 20, 2018

Received: March 22, 2018

Dear Susan Quick:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

Enclosure

## Indications for Use

510(k) Number (if known)

K173079

Device Name

Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4

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. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent.

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 of Safety and Effectiveness

# K173079

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

<b>Date Prepared:</b>	September 27, 2017	
<b>Manufacturer:</b>	Philips Medical Systems Nederland B.V. Veenpluis 4-6, 5684 PC, Best, The Netherlands Establishment Registration Number: 3003768277	
<b>Primary Contact Person:</b>	Jan van de Kerkhof Sr. Manager Regulatory Affairs Phone: +31 613300542 E-mail: <a href="mailto:jan.van.de.kerkhof@philips.com">jan.van.de.kerkhof@philips.com</a>	
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<b>Device Name:</b>	Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4	
<b>Classification:</b>	Classification name:	Magnetic Resonance Diagnostic device (MRDD)
	Classification Regulation:	21CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	90LNH 90LNI
<b>Primary Predicate Device:</b>	Trade name:	Ingenia 1.5T, Ingenia 1.5T S, Ingenia 3T R5.3
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K163116
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II
Product Code:	90LNH 90LNI	

<p><b>Device Description:</b></p>	<p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with Compressed SENSE feature is applicable for the 60 cm (CX) and 70 cm magnet systems. The systems and control software are substantially equivalent to the legally marketed primary predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017).</p> <p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature also includes minor software changes since the clearance of the legally marketed primary predicate device, Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017).</p> <p>The following modifications are covered in this submission:</p> <ol style="list-style-type: none"> <li>1. Upgrade software platform to Windows 10</li> <li>2. Compressed SENSE feature allows ultra-high acceleration factors for shorter scan times and higher resolution in 2D and 3D imaging based on the principle of Compressed sensing in combination with SENSE.</li> <li>3. PerformanceBridge Protocol Manager Release 1.0 offering intended to help customers increase collaboration within a healthcare facility group. Customers will enter the Protocol Manager cloud functionality via the PerformanceBridge portal.</li> </ol> <p>Protocol Manager is a subscription service to a cloud based protocol repository that will allow a user to standardize protocols over the various connected MRI systems, enable editing of protocols and scan parameters and make central protocols available for use on local MRI systems.</p> <p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T, Ingenia 1.5T CX, and Ingenia 3.0T CX R5.4</b> with Compressed SENSE feature is intended to be marketed with the following pulse sequences and coils that were previously cleared by FDA:</p> <ol style="list-style-type: none"> <li>1. mDIXON K102344</li> <li>2. SWIp K131241</li> <li>3. mDIXON-Quant K133526</li> <li>4. MRE K140666</li> <li>5. mDIXON XD K143128</li> <li>6. O-MAR K143253</li> <li>7. MultiBand SENSE K143606</li> <li>8. Ingenia Coils See Appendix 004 and Appendix 007</li> </ol>
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<b>Indications for Use:</b>	<p>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.</p> <p>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.</p> <p>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. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent.</p> <p>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.</p> <p>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.</p>
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<p><b>Design Features/ Fundamental Scientific Technology:</b></p>	<p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature are 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.</p> <p>The principal technological components (magnet, transmit body coil, gradient coil, receive coils and patient support) of the proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature are identical to those used in the legally marketed primary predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017).</p> <p>Compressed SENSE enables scan time reduction or improved spatial resolution through non-equidistant k-space sampling and regularized reconstruction methods with automatic parameter tuning. The Compressed SENSE feature allows ultra-high acceleration factors for shorter scan times and higher resolution in 2D and 3D imaging based on the principle of Compressed sensing in combination with SENSE. The use of Compressed SENSE is limited to non-contrast enhanced exams.</p> <p>Based on the information provided above, the proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature does not raise different questions of safety and effectiveness compare to the legally marketed primary predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017).</p>
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<p><b>Summary of Non-Clinical Performance Data:</b></p>	<p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature comply with the following international and FDA-recognized consensus standards:</p> <ul style="list-style-type: none"> <li>• IEC60601-1-2 Edition 3</li> <li>• IEC60601-1-6 Edition 3</li> <li>• IEC62366 (2015)</li> <li>• IEC60601-1-8 Edition 2</li> <li>• IEC60601-2-33 Edition 3</li> <li>• IEC 62304 (2006)</li> <li>• ISO 14971 Application of risk management to medical devices (2007)</li> <li>• Device specific guidance document, entitled “Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 18, 2016”</li> <li>• Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005)</li> <li>• Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices 9 issued February 3, 2016)</li> <li>• Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued October 2, 2014</li> </ul> <p>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.</p> <p>The verification and or validation test results, combined with sample clinical images demonstrate that the proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature:</p> <ul style="list-style-type: none"> <li>• 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 18, 2016”</li> <li>• Meets the acceptance criteria and is adequate for its intended use.</li> </ul> <p>Therefore, the proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature are substantially equivalent to the legally marketed primary predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017) in terms of safety and effectiveness.</p>
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<p><b>Summary of Clinical Data:</b></p>	<p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature did not require a clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.</p>
<p><b>Substantial Equivalence:</b></p>	<p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature and the legally marketed primary predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017) have the same indications for use with respect to the following:</p> <ul style="list-style-type: none"> <li>• Providing cross-sectional images based on the magnetic resonance phenomenon</li> <li>• Interpretation of the images is the responsibility of trained physicians</li> <li>• Images can be used for interventional and treatment planning purposes</li> </ul> <p>The proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature are substantially equivalent to the legally marketed primary predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3T R5.3 (K163116, 01/06/2017) 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.</p>
<p><b>Conclusion:</b></p>	<p>The results of these tests demonstrate that the proposed <b>Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4</b> with the Compressed SENSE feature meet the acceptance criteria and is adequate for its intended use.</p>