Philips Medical Systems Nederland B.V.
Susan Quick
Regulatory Affairs Specialist
595 Miner Rd
Cleveland, Ohio 44143

February 14, 2019

Re: K183063
Trade/Device Name: Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: November 2, 2018
Received: November 5, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183063

Device Name

Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition

Indications for Use *(Describe)*

Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system enables trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing 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, the MR scan technique applied, and presence of contrast agents. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent.

The trained clinical user can adjust the MR scan parameters to customize image appearance, accelerate image acquisition, and synchronize 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 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.

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

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

Date Prepared:	October 26, 2018	
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**	Jan van de Kerkhof Sr. Manager Regulatory Affairs Phone: +31 613300542 E-mail: jan.van.de.kerkhof@philips.com Susan Quick Regulatory Affairs Specialist Telephone: 440 869-4612 E-mail: susan.quick@philips.com	
Device Name:	Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems	
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:	Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K173079
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	90LNH 90LNI
Reference Device:	Trade name:	Ingenia Eilition S, Ingenia Elition X
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K173451
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II

	Product Code:	90LNH 90LNI
Reference Device:	Trade name:	Ingenia Ambition S, Ingenia Ambition X
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K180479
	Classification Regulation:	21CFR 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, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** with bFFE-XD, IRIS Zoom, MEGA, SENC, and SyntAc software features are provided on the 60 cm and 70 cm bore 1.5 Tesla (1.5T) and 3.0 Tesla (3.0T) MR systems. The systems and aforementioned software features of the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device, Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018) and the legally marketed reference devices Ingenia Elition S and Ingenia Elition X (K173451, 03/20.2018) and the Ingenia Ambition S and Ingenia Ambition X (K180479, 08/03/2018) . Hereafter **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.6** with SENC, bFFE XD, IRIS ZOOM, MEGA and SyntAc software features will be referred to as the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** in this submission. This submission includes the software modifications below for the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems,** there are no hardware changes: 1. bFFE-XD 2. IRIS Zoom 3. MEGA 4. SENC (Spiral Cardiac) 5. SyntAc (MDME)* * This software feature is provided on the proposed Ingenia systems only (Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T and Ingenia 3.0T CX). Please note that this feature is already cleared and legally marketed on Ingenia Ambition and Elition systems. The proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** submission also includes minor changes to the existing software features listed below since the clearance of the legally marketed predicate device,

	Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018): 1. VAPOR 2. sLASER 3. Spiral Brain 4. 3D Non-selective 5. Diffusion XD TSE 6. 2KDTI 7. Advanced diffusion gradient control 8. K-t SENSE 9. Cardiac ZOOM 10. Retrospective EPI 11. mFFE Echo Summation* 12. Contrast Card* 13. Autostart* * This software feature is provided on the proposed Ingenia systems only (Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T and Ingenia 3.0T CX). Please note that this feature is already cleared and legally marketed on Ingenia Ambition and Elition systems. The proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are intended to be marketed with the following pulse sequences and coils that were previously cleared by FDA: 1. mDIXON (K102344) 2. SWIp (K131241) 3. mDIXON-Quant (K133526) 4. MRE (K140666) 5. mDIXON XD (K143128) 6. O-MAR K143253 7. MultiBand SENSE (K143606) 8. 3D APT (K172920) 9. Ingenia Coils, see Appendix 011
Indications for Use:	There are minor modifications to the indications for use statement for the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** for clarity, but the intended use has not changed. Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system enables trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing 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, the MR scan technique applied, and presence of contrast agents. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent.

	The trained clinical user can adjust the MR scan parameters to customize image appearance, accelerate image acquisition, and synchronize 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 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. 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.
Design Features/ Fundamental Scientific Technology:	The proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** 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. The principal technological components (magnet, transmit body coil, gradient coil, receive coils and patient support) of the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are identical to those used in the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018), and the legally marketed reference devices Ingenia Elition S and Ingenia Elition X (K173451, 3/20.2018) and the Ingenia Ambition S and Ingenia Ambition X (K180479, 08/03/2018). The following are descriptions of the modified or minor enhanced software features. The main application of **bFFE XD** is to reduce banding artifacts, resulting from the B0 sensitivity of balanced Fast Field Echo (bFFE) sequences. Those black band artifacts can obscure information in the images. The main clinical application targeted by bFFE XD is high resolution 3D inner ear (auditory canal) imaging. **IRIS ZOOM** is an improvement of Zoom Diffusion Imaging in the spine. Due to the multi-shot capability, IRIS ZOOM delivers a higher resolution, lower distortion and improved fat suppression in spine when compared to Zoom Diffusion Imaging.

	MEGA is a feature that allows for detection of J-coupled metabolite signals like GABA (gamma-butyric acid) in the brain. MEGA is spectral editing technique and intended for single voxel 1H spectroscopy in the brain on 3T systems. **SENC** (Strain ENCoding) is intended for cardiac imaging, to measure cardiac muscle contraction as a function of time within the cardiac cycle. **SENC** produces strain encoded images. Those images are processed by 3rd party software MyoStrain to produce strain analysis and reporting. The **SyntAc (MDME)** gives possibility to acquire Multi-Dynamic Multi-Echo (MDME) images. These images can be processed by 3rd party (Synthetic MRI) software to produce the relevant radiological contrasts. **VAPOR** is an enhancement of the Philips Excitation implementation and is designed to be less sensitive to T1 variations and B1 inhomogeneities. **sLASER** is a modification of 1H SE (PRESS) localized spectroscopy and can be applied to Single Voxel Spectroscopy (SV) as well as Spectroscopic Imaging (MRSI). The **sLASER** sequence uses slice selective adiabatic pairs of refocusing RF pulses to reduce the chemical shift displacement up to a factor 4 when compared to PRESS-localized spectroscopy at 3T. **Spiral Brain** uses a spiral readout, which is applied as an alternative to the Cartesian k-space traversal pattern. Some of the general benefits of spiral vs. Cartesian MRI include (1) faster scans, due to longer readout time and (2) image artifact robustness, due to reduced flow sensitivity). **Spiral Brain** leverages those benefits to enhance T1 SE sequences in the brain at 1.5T and 3T. **3D Non-selective** excites the entire volume using a very short RF pulse in 3D FFE brain imaging. Due to the resulting shorter TR and shorter TE, **3D Non-selective** delivers a faster protocol and improved grey-white matter contrast in 3D TFE. **Diffusion XD TSE** technique is an enhancement of Diffusion TSE. It introduces the SPLICE technique and enables the combination with a MultiVane readout. By allowing the combination with MultiVane, a multi-shot readout can be achieved, which contributes to the sharpness of the resulting image and includes intrinsic motion correction. **2KDTI** is a technical enhancement of the maximal number of diffusion encodings that can be collected in one diffusion scan. **2KDTI** provides up to 2048 independent diffusion encodings (vectors) with up to 1024 different weightings and 1024 different directions. **Advanced diffusion gradient control** allows the scientific user to select from multiple diffusion encoding gradient waveforms. **Advanced diffusion gradient control** enables the user to define manually the duration of the diffusion encoding gradients. **k-t SENSE** is a spatio-temporal acceleration technique that combines the benefits of k-t BLAST with the better image uniformity capabilities of SENSE.

	Reconstruction-wise, the k-t BLAST works on a coil by coil basis. **k-t SENSE** processes the coils (coil elements) integrally with the help of which the homogeneity of the images are enhanced. **Cardiac ZOOM** is a small FOV imaging technique which performs the excitation and refocussing pulses orthogonally. **Cardiac ZOOM** enhances black blood imaging, by providing accelerated and single beat imaging. This allows scanning of patients who cannot hold their breath. **Retrospective cardiac gating** synchronizes pulse sequence with cardiac rhythm so that cardiac motion related artifacts are removed. **Retrospective gating** is enhanced by allowing the combination with EPI and TFE-EPI sequences, which are used to explore 4D flow imaging. Multiple echoes from an FFE scan can be summed to calculate a new image. **mFFE Echo Summation** automates this echo combination via a root-sum-of-squares echo summation in reconstruction SW. This delivers an enhanced workflow when compared to the existing manual post-processing that is available in Image Algebra post-processing package. The **Contrast Card enhancement** offers the ability to add information on the contrast agent. After applying the contrast agent, which is done independent from the MR system, information on the applied contrast is added to the DICOM images. When viewing these images on the MR system the images, which have been taken while contrast was applied, are marked with an indication “Contrast”. After pressing Start Scan at the controls at the magnet façade the scan will automatically start (**Autostart feature**) when the RF door is closed. This function is the same as the legally marketed reference device Ingenia Elition S and Ingenia Elition X systems (K173451, 03/20/2018) and for the Ingenia Ambition S and Ingenia Ambition X systems (K180479, 08/03/2018) and is implemented without further changes. Based on the information provided above, the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** do not raise different questions of safety and effectiveness compared to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018).
Summary of Non-Clinical Performance Data:	The proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** complies with the following international and FDA-recognized consensus standards: • IEC60601-1 Edition 3 • IEC60601-1-2 Edition 4 • IEC60601-1-6 Edition 3 • IEC62366-1 Edition 1 • IEC60601-1-8 Edition 2 • IEC60601-2-33 Edition 3 • IEC 62304 Edition 1 • NEMA MS-1 2008 • NEMA MS-4 2010

	• NEMA MS-8 2008 • NEMA PS 3.1-PS 3.20 • ISO 14971 Edition 2 • Device specific guidance document, entitled "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices" (issued November 18, 2016 – document number 340) • Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005 – document number 337) • Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014 – document number 1825) • Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices (issued February 3, 2016 – document number 1757) • Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued June 16, 2016 – document number 1811) • Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (issued July 11, 2016 – document number 1400057) • Guidance for Industry and FDA Staff – Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices (issued September 6, 2017 – document number 1500015) 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. The verification and/or validation test results demonstrate that that the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems**: • Comply 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" • Meet the acceptance criteria and is adequate for its intended use. Therefore, the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** did not require a clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.
Substantial Equivalence:	The proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** and the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S,

Conclusion:	Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018) have the same 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 **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T, and Ingenia 3.0T CX R5.4 (K173079, 04/04/2018) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence is 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, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** meet the acceptance criteria and are adequate for their intended use.