Philips Medical Systems Nederland BV
% Ms. Susan Quick
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

April 10, 2020

Re: K193215
Trade/Device Name: Achieva, Intera, Ingenia, Ingneia 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, LNI
Dated: March 11, 2020
Received: March 12, 2020

Dear Ms. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K193215

Device Name
Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems

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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Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems

Section 5

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:	November 14, 2019	
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:	Achieva, Intera, 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, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K183063
	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:	MultiBand SENSE
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K162940
	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 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T CX, 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

Device Description:	The proposed **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7** with MultiBand SENSE software feature are provided on the 60 cm and 70 cm bore 1.5 Tesla (1.5T) and 3.0 Tesla (3.0T) Magnetic Resonance Diagnostic Devices. Hereafter **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7** with MultiBand SENSE software feature will be referred to as the proposed **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** in this submission. This bundled abbreviated 510(k) submission will include software modifications to the following legally marketed MR systems: Ingenia 1.5T, Ingenia 1.5T S, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S and Ingenia Ambition X (K183063, 02/14/2019) and Achieva 1.5T, Achieva 3.0T, Intera 1.5T (K190461, 06/04/2019). All of the aforementioned legally marketed systems will be brought up to the new baseline software R5.7. This submission addresses only software modifications, there are no hardware modifications made to any of the above legally marketed systems. In this 510(k) submission, Philips Medical Systems Nederland B.V. will be addressing modifications to MultiBand SENSE and one labeling change to the proposed **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems**: • Removal of contra-indication statement of Compressed SENSE with Gd contrast agent This 510(k) submission will also address minor software enhancements contained in software R5.7 for the proposed **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** since the clearance of the last submission for each of the systems: 1. 4D FreeBreathing

	2. MR Elastography Extension 3. EPIC Brain 4. LOVA ADC 5. Computed DWI 6. SmartShim 7. VitalScreen 8. Extended Functionality Options 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. mDIXON XD (K143128) 5. O-MAR K143253 6. 3D APT (K172920) 7. Ingenia Coils The proposed **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K183063, 02/14/2019). In addition, the proposed **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems is substantially equivalent to the following** legally marketed reference devices: • MultiBand SENSE software application (K162940, 12/30/2016), to support MultiBand SENSE for 1.5T and to support diffusion body imaging on 1.5T and 3.0T. • Ingenia 1.5T, Ingenia 1.5T S, Ingenia 1.5T CX, Ingenia 3.0T CX, and Ingenia 3.0T CX R5.4 K173079, 04/04/2018, to support the removal of the contra-indication of the compatibility of Compressed SENSE with (dynamic) Gadolinium contrast-enhanced imaging.
Indications for Use:	There are no modifications to the indications for use statement for the proposed **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems**. *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 **Achieva, Intera**, **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 **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are identical to those used in the legally marketed predicate device Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K183063, 02/14/2019. The following are descriptions of the labeling change or descriptions of the modified or minor enhanced software features. **Compressed SENSE with Contrast** Faster scanning in the presence of Gadolinium-based contrast agents can be achieved using **Compressed SENSE**. The sequence and reconstruction implementations are identical to those used for previously-cleared Compressed SENSE for native contrasts, and do not include sparse sampling and signal combination in the temporal domain. Compressed SENSE provides accurate temporal and spatial resolution, and contrast appearance. The contra-indication for compatibility of Compressed SENSE with (dynamic) Gadolinium contrast-enhanced imaging will be removed from the Instructions for Use.

	MultiBand SENSE Multiband SENSE allows acceleration factors in single shot EPI sequence in DWI, DTI and fMRI. MultiBand SENSE is allowed on 3.0T and 1.5T DDAS systems. This function is the identical as the legally marketed device MultiBand and is now also implemented with minor changes on the 1.5T systems. The minor change is limiting the allowed MultiBand factor to 2 on 1.5T systems. **MultiBand SENSE Extension** MultiBand SENSE Extension is an extension of MultiBand SENSE which enables exploring diffusion imaging in the body. **VitalScreen** The Coil and Accessories Guidance was added to guide the user to correctly position mattresses and connecting coils. **4D FreeBreathing** 4D FreeBreating technology uses 3D FFE and TFE radial acquisitions (like in 3D Vane XD) to avoid image artifacts typically seen with Cartesian imaging (Like 4D Thrive) when the patient cannot hold their breath. The MR technique enables dynamic imaging multiple contrast phases of the body without the need for the patient to hold their breath. **MR Elastography Specialist** Elastography Specialist has been enhanced with the SE-EPI sequence. The SE-EPI sequence is an alternative to the already available FFE sequence to perform elasticity assessment of the liver with MR. **Epic Brain** EPIC Brain corrects for geometrical distortions in EPI scans. **LOVA ADC** LOVA ADC corrects for gradient non-linearities so to produce more accurate ADC maps. **Computed DWI** Computed DWI is used to compute high b-value diffusion images, so to save scan time. **SmartShim** SmartShim is an automated shimming technology to correct for B0 inhomogenieties. **SmartExam Packages** The SmartExam Packages for Brain, Spine, Shoulder, Knee and Breast have been enhanced by providing a faster SmartSurvey scan, so to save examination time. The SmartSurvey is accelerated by using Compressed SENSE technology. **FFE Extensions** Extends the parameter space for m-FFE to allow more than 32 echoes.

	TFE Extensions Extends the parameter space for product TFE to enable randomized k-space segmentation and CENTRA turbo-direction. **SE Extensions** Extends the parameter space to enable LIPO for non-DWI SE. **TSE Extensions** Extends the parameter space for TSE to enable DRIVE pre-pulse extensions and to enable user-defined contrasts for 3DView. **Diffusion Extensions** Extends the parameter space for DWI/DTI with dynamic imaging. **Angio Extensions** Extends the parameter space for eTHRIVE and 4D TRAK with profile order CENTRA. **Weighted Gating Navigator Extensions** Extends the parameter space for respiratory gating by allowing k-space weighting. **EPI/GraSE Extensions** Extends the parameter space for GraSE to allow more TSE profile orders (low-high or asymmetric). **Spiral Extensions** Extends the parameter space for Spiral Brain to allow use without brain coils, and to allow the combination with quantitative flow or diffusion. **Respiratory Gating** Extends the parameter space for respiratory gating for cardiac triggered scans. **Fast Next Scan Extensions** Extends the parameter space of BolusTrak by allowing a MS or 3D in the BolusTrak scan. **Custom Prepulse** Extends the parameter space for Prepulse by allowing the user to specify the pre-pulse or specify a Multi-pulse off-resonance MTC pulse. **B0 map & Shim Extensions** Extends the parameter space for B0 field mapping, used for breast and brain, to other applications. Extends the parameter space for higher order shimming at 3.0T by allowing user to set shim values. **K-t Blast/k-t SENSE Extensions** Extends the parameter space for product k-t BLAST/k-t SENSE by allowing extension of acceleration factor allowing Qflow.

	Radial Extensions Extends the parameter space for radial to enable multi slice scans and to enable ultra-short echo times. **mDIXON TSE Extensions** Extends the parameter interface for mDIXON TSE to enable the combination with 3D, cardiac triggering and respiratory compensation. **Multivane XD Extensions** Extends the parameter interface to MultiVane to combine with cardiac synchronization and with respiratory navigator compensation. **Automatic Planning Extensions** Extends the parameter interface for SmartExam by allowing user to define the SmartScout scan. **mDIXON CENTRA Keyhole** Extends the parameter interface for 4D Trak XD by allowing the combination with mDIXON. Based on the information provided above, the proposed **Achieva, Intera**, **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, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K183063, 02/14/2019), therefore demonstrating substantial equivalence.
Summary of Non-Clinical Performance Data:	Please note that the Achieva and Intera MR Systems are no longer being manufactured but at the time of manufacture and release of these systems, the Achieva and Intera MR Systems were in compliance with the international and FDA recognized consensus standards. This proposed submission is to release the updated software features to the install base of the Achieva and Intera MR Systems. Philips Medical Systems Nederland B.V. declares that the proposed **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are in compliance with all applicable requirements of the following international and FDA recognized consensus standards: **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition** • 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) • Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005) • Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 18 2018) • Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices (issued February 3, 2016) • 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) • Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (issued July 11, 2016) • Guidance for Industry and FDA Staff –(issued September 6, 2017) All software modifications were tested across MR system families (Achieva, Ingenia, Elition and Ambition). Non-Clinical verification and or validation tests have been performed on all of the software modifications with regards to the intended use, the technical claims, the requirement specifications and the risk management results. The results from each set of tests demonstrate that the software features perform as intended and are therefore substantially equivalent to the predicate devices to which they have been compared. For Compressed SENSE with contrast, bench test results (Shelley phantom), using both retrospectively and prospectively sub-sampled data, demonstrating adequate capture of time-intensity behavior were provided. Philips provided data from retrospective sub-sampled CE-angio data, on 3 human subjects. This allowed for a direct comparison of SENSE and Compressed SENSE in terms of difference images relative to non-accelerated, fully sampled data. Compressed SENSE was shown to be more robust up to higher acceleration factors. Using a retrospective subsampling approach, clinical data for brain perfusion in tumor classification was provided. Philips believes that the analysis and data from all testing demonstrates equivalence of CS-SENSE with the predicate device (non-accelerated data acquisition) for this dynamic contrast uptake application. Test results demonstrate that the proposed **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** meet the acceptance criteria and are adequate for its intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated and that no new risks are introduced, and that the overall residual risks are acceptable.

	Therefore, the proposed **Achieva, Intera Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K183063, 02/14/2019) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **Achieva, Interan, 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 **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** and the legally marketed predicate device Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K183063, 02/14/2019) 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
Conclusion:	The proposed **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems (K183063, 02/14/2019) 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 **Achieva, Intera**, **Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems** meet the acceptance criteria and are adequate for their intended use.