Philips Medical Systems Nederland, B.V.
℅ Susan Quick
Sr. Manager Regulatory Affairs
Veenpluis 4-6
5684PC Best
NETHERLANDS

May 16, 2022

Re: K213583
Trade/Device Name: Achieva, 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, LNI
Dated: April 14, 2022
Received: April 15, 2022

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/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
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213583

Device Name

Achieva, 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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K213583

Achieva, 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:	Nov. 10, 2021	
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 Telephone: +31 613300542 E-mail: jan.van.de.kerkhof@philips.com Susan Quick Regulatory Affairs Specialist Telephone: (440) 8694612 E-mail: susan.quick@philips.com	
Device Name:	Achieva, 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:	Achieva, Intera, Ingenia, Ingneia CX, Ingenia Elition, And Ingenia Ambition MR Systems R5.7
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K193215
	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, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems R11.0** are 60 cm and 70 cm bore 1.5 and 3.0 Tesla (1.5T and 3.0T) Magnetic Resonance Diagnostic Devices, hereafter to be known as **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems**. This bundled abbreviated 510(k) submission will include modifications of the **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** as compared to our legally marketed devices **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020)**. In this 510(k) submission, Philips Medical Systems Nederland B.V. will be addressing the following minor software enhancements to the proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** when compared to the legally marketed predicate **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020):** 1. SmartSpeed AI 2. SmartSpeed MotionFree 3. SmartSpeed 3D FreeBreathing 4. SmartSpeed Implant 5. SmartSpeed DWI 6. MR Workspace 7. ISP MR Packages 8. Extended functionality Options This 510(k) submission will also address the following minor hardware enhancements: 1. Introduction of a graphical processing unit in the host recon computer for image reconstruction 2. Additional monitor as part of the operating console The supporting documentation provided for the proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems,** includes software and hardware modifications that are addressed in test reports for system level development project, Voyager. The proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** are intended to be marketed with the following pulse sequences and coils that are 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. 3D APT (K172920) 8. Compatible System Coils
Indications for Use:	There are no changes to the indications for use statement, provided below, of the proposed **Achieva, 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, 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, gradient amplifier, RF amplifier and patient support) of the proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** are identical to those used in the legally marketed predicate device **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR systems R5.7 (K193215, 04/10/2020).** The software R11 used on the proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** has been modified to include the SmartSpeed AI feature combining the previously cleared and legally marketed feature Compressed-SENSE (K193215, 04/10/2020) with machine learning to allow for higher accelerations with equal or better image quality.
Summary of Non-Clinical Performance Data:	The proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** are compliance 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 SmartSpeed AI feature has undergone performance testing on component and system level. A variety of datasets from different anatomies and image contrasts, varying SNR levels and acceleration factors were reconstructed with and without SmartSpeed AI and compared to fully sampled ground truth data. A pixel-wise comparison was performed to confirm that SmartSpeed AI does provide comparable or better results than the data reconstructed without SmartSpeed AI. SmartSpeed AI showed better alignment with the ground truth data for high acceleration factors and low SNR levels compared to the data reconstructed without SmartSpeed AI. In vivo images were analyzed to confirm that SmartSpeed AI does not negatively impact image quality measures when acquired with reduced scan time. A reader evaluation study with US board certified radiologists was performed on SmartSpeed AI images acquired across a variety of pulse sequences and anatomies. Radiologists were asked to perform comparisons of SmartSpeed AI images acquired with shorter scan times and images without SmartSpeed AI acquired with longer scan times. The combined results of the comparison described above confirmed that the SmartSpeed AI feature provides images with equivalent or better image quality. The verification and/or validation test results demonstrate that the proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia**

	Ambition MR Systems meet the acceptance criteria and are adequate for the intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated; that new risks that were identified are mitigated to an acceptable level; and that the overall residual risk is acceptable. Therefore, the proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate devices **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR systems R5.7 (K193215, 04/10/2020)**, in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed Ingenia **Achieva, 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: **Conclusion:**	The proposed **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** and the legally marketed predicate device **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR systems R5.7 (K193215, 04/10/2020)**, 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 **Achieva, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** are substantially equivalent to the legally marketed predicate device **Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR systems R5.7 (K193215, 04/10/2020)**, 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, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems** meet the acceptance criteria and are adequate for the intended use.