July 11, 2025

Philips Medical Systems Nederland B.V.
Mehmet Caner Cagdanlioglu
Regulatory Affairs Manager
Veenpluis 6
Best, 5684 PC
Netherlands

Re: K251808
Trade/Device Name: Achieva; Intera; Ingenia 1.5T; Ingenia 3.0T; Ingenia 1.5T CX; Ingenia 3.0T CX; Ingenia Elition S; Ingenia Elition X; Ingenia Ambition S; Ingenia Ambition X; and MR 5300 MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: June 12, 2025
Received: June 12, 2025

Dear Mehmet Caner Cagdanlioglu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ningzhi Li -S

Digitally signed by Ningzhi Li -S

for
Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251808

Please provide the device trade name(s).

Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems

Please provide your Indications for Use below.

Indications for Use:

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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary **K251808**

The 510(k) Summary was prepared in accordance with 21 CFR §807.92(c).

Preparation date:	July 11, 2025	
510(k) Owner:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC, Best, The Netherlands Establishment Registration Number: 3003768277	
Contact person(s):	Mehmet Caner Cagdanlioglu *(primary)* Regulatory Affairs Manager Phone: +31 634590388 E-mail: mehmetcaner.cagdanlioglu@philips.com Leo Louis *(secondary)* Director Regulatory Affairs Phone: +31 687945888 E-mail: Leo.Louis@Philips.com	
Device Name:	Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems	
Classification:	**Classification Name:**	Magnetic Resonance Diagnostic Device (MRDD)
	Regulation Number:	21 CFR 892.1000
	Review Panel:	90-Radiology
	Device Class:	Class II
	Primary Product Code:	LNH
	Secondary Product Code:	LNI
Primary Predicate Device	**Trade Name:**	MR 5300 MR Systems
	510(k) Clearance:	K212673
	Manufacturer:	Philips Medical Systems Nederland B.V.
	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Regulation Number:	21 CFR 892.1000

	Device Class:	Class II
	Primary Product Code:	LNH
	Secondary Product Code:	LNI
Secondary Predicate Device	**Trade Name:**	Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems
	510(k) Clearance:	K193215
	Manufacturer:	Philips Medical Systems Nederland B.V.
	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Review Panel:	90-Radiology
	Regulation Number:	21 CFR 892.1000
	Device Class:	Class II
	Primary Product Code:	LNH
	Secondary Product Code:	LNI

The primary and secondary predicate device are hereafter called “predicate devices” when intended to be used together.

Device description

The subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** are 60 cm and 70 cm bore 1.5 and 3.0 Tesla (1.5T and 3.0T) Magnetic Resonance Diagnostic Devices.

In this 510(k) submission, Philips Medical Systems Netherlands B.V. will be addressing the following software changes for the subject device since the last 510(k) submission (primary predicate device (K212673, 11/19/2021), secondary predicate device (K193215, 04/10/2020)):

- Software functionality that allows early detection of severe gradient malfunctions. The system is locked for scanning if a malfunction is detected.
- Smoke detector software support extension from Ingenia Elition S and X to all other 70cm bore systems
- SENSE XL Torso Coil workflow extensions to guide the operator on safe usage of the SENSE XL Torso Coil and monitoring of the SENSE XL Torso Coil temperature

The subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** are intended to be marketed with the same pulse sequences and coils that are previously cleared by FDA:

The accessories to be used with the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia**

Ambition X and MR 5300 MR Systems have not changed compared to the predicate device and can be found in the Instructions for Use accompanying the device.

When Philips MRI system is used in combination with the Philips MR-RT or MR-OR solutions, the user is referred to the dedicated MR-RT and MR-OR Instructions for Use for information on additional accessories that may apply.

Indications for use

The indications for Use statement provided below for the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** is identical to the predicate devices. The intended use is also not impacted by the introduction of software changes as described in section Device Description.

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:

Same as the predicate device, the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** 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, gradient amplifier, RF amplifier and patient support) of the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** is unchanged compared to predicate device.

Summary of Non- Clinical Performance Data:

Non-clinical performance testing has been performed on the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** and demonstrates compliance with following international and FDA-recognized consensus standards:

Recognition Number	Standard Number and Date	Standard Name
5-132	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	*Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
13-79	ANSI AAMI IEC 62304:2006/A1:2016	*Medical device software - Software life cycle processes [Including Amendment 1 (2016)]*
5-129	ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	*Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1*
5-125	ANSI AAMI ISO 14971: 2019	*Medical devices – Application of risk management to medical devices.*
5-134	ISO 15223-1:2021, 15223-1 Fourth Edition 2021-07	*Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*
5-135	ISO 20417 First Edition 2021-04 Corrected version 2021-12	*Medical devices - Information to be supplied by the manufacturer*

Non-Clinical verification and 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 the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** meet the acceptance criteria and are adequate for the intended use.

The risk management activities show that all risks are sufficiently mitigated, that no new risks are introduced, and that the overall residual risks are acceptable.

Therefore, the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** are substantially equivalent to the legally marketed predicate devices in terms of safety and effectiveness.

Summary of Clinical Data:

With the subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems**, the indications for use remain unchanged and there were no technological characteristics relative to the predicate device that would require clinical testing.

Substantial Equivalence:

The subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** and the legally marketed predicate devices 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 table below provides a comparison overview between the subject and predicate device for the software feature changes together with a rationale for why the differences do not raise different questions of safety and effectiveness and a conclusion on substantial equivalence.

Table Technological characteristics comparison between subject and predicate device for software changes

Primary Predicate device *(K212673, November 19, 2021) and* Secondary Predicate Device *(K193215, April 10, 2020)*	**Subject device**	**Conclusion on substantial equivalence**
Smoke Detector Interlock		
• Smoke Detector Interlock software for 60cm MR Systems. • The Smoke Detector Interlock reduced the risk of fire against abnormal use by ensuring that it is only possible to resume scanning after a Field Service Engineer has confirmed that no hazardous situation exists anymore. • The IfU (Instructions for Use) and UI have been updated for clarity with improved instructions to the user in case smoke is detected. • The PD-Break Heat Detector further reduced the risk to ensure that the system does not allow scanning before even smoke occurs. *Note: The same smoke detector Interlock software technology has been implemented in the following reference devices: K230972 and K232030.*	**Similar** The Smoke Detector Interlock software is implemented on 70cm MR Systems.	**Equivalent** The implementation of the Smoke Detector Interlock software in the 70cm MR Systems of the subject device is the same compared to the predicate device for 60cm MR Systems. The difference between the 60cm and 70cm MR Systems does not raise any new questions regarding safety and effectiveness as the smoke detector technology is the same in both devices.
Severe Gradient Malfunction Detection		
The MR System aborts on individual errors from the gradient amplifier and will reset and allow customer to continue.	**Similar** MR System aborts individual errors from the gradient amplifier and will reset and allow customers to continue. The newly added additional check via the severe	**Equivalent** Similar as the predicate device, the subject device aborts individual errors from the gradient amplifier and will reset and allow customers to continue. The additions in the subject device do not impact the intended use of the

Table Technological characteristics comparison between subject and predicate device for software changes

Primary Predicate device *(K212673, November 19, 2021) and* Secondary Predicate Device *(K193215, April 10, 2020)*	**Subject device**	**Conclusion on substantial equivalence**
	gradient malfunction detection functionality will lock the subject device. When the frequency of occurrence of errors from this subset goes beyond predefined thresholds, then the MR Systems will be preventively locked to avoid severe gradient malfunction to occur.	device, nor does it raise any new questions of safety and effectiveness.
SENSE XL Torso Coil		
Before and during the examinations, the MR System software does not warn the operator upfront and does not keep track of the SENSE XL Torso Coil temperature during usage.	**Similar** The MR System software enforces a cool down period for the coil when the temperature reaches a level that would go beyond an acceptable level in the next examination. In addition, the temperature information is used to guide the operator suggesting it is advised to stop the examination and enforce cool down to enable the operator to stay within acceptable temperature limits during an examination.	**Equivalent** The implementation of additional operator guidance on the usage of the SENSE XL Torso coil and monitoring of the temperature does not impact the intended use of the device, nor does it raise any new questions of safety and effectiveness.

Based on the comparison described above Philips Medical Systems Nederland B.V. believes that the subject device is substantially equivalent to the predicate devices in terms of:

- Intended Use / Indications for Use,
- Technological characteristics,
- Safety and effectiveness.

Conclusion:

The subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** are substantially equivalent to the legally marketed predicate devices 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 subject **Achieva, Intera, Ingenia 1.5T, Ingenia 3.0T, Ingenia 1.5T CX, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition S, Ingenia Ambition X and MR 5300 MR Systems** meet the acceptance criteria and are adequate for the intended use.