



June 4, 2025

Philips Medical Systems Nederland B.V.
Liselotte Kornmann
Regulatory Affairs Manager
Veenpluis 6
Best, 5684PC
Netherlands

Re: K251397

Trade/Device Name: Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR System

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: Class II

Product Code: LNH, LNI

Dated: May 2, 2025

Received: May 6, 2025

Dear Liselotte Kornmann:

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent 'FDA' watermark.

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.

K251397

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Please provide the device trade name(s).

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Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR System

Please provide your Indications for Use below.

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The Indications for Use statement provided below for the proposed device is identical to the one of the primary and secondary predicate devices. The intended use is also not impacted by the introduction of SmartSpeed Precise feature.

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)

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510(k) Summary

K251397

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

Preparation date: May 6, 2025
510(k) Owner: Philips Medical Systems Nederland B.V.
Veenpluis 6, 5684 PC, Best, The Netherlands
Establishment Registration Number: 3003768277

Contact person(s): Liselotte Kornmann (*primary*)
Regulatory Affairs Manager Strategy
Phone: +31 611621238
E-mail: Liselotte.Kornmann@philips.com

Leo Louis (*secondary*)
Director Regulatory Affairs
Phone: +31 687945888
E-mail: Leo.Louis@Philips.com

Device Name: Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR System

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

Predicate Device **Trade Name:** Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, MR 5300 and MR 7700 MR System
510(k) Clearance: K223458
Manufacturer: Philips Medical Systems Nederland B.V.
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

Device description

The subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** are 60 cm and 70 cm bore 1.5 and 3.0 Tesla (1.5T and 3.0T) Magnetic Resonance Diagnostic Devices.

A new optional software feature SmartSpeed Precise is contained in software R12.3 for the subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems**.

SmartSpeed Precise is a machine learning based reconstruction technique designed to increase the signal-to-noise (SNR), increase the sharpness, and reduce residual ringing artifacts in MR images.

The introduction of *SmartSpeed Precise* only required updates to the MR System Software.

The subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** is identical to the predicate devices. The intended use is also not impacted by the introduction of SmartSpeed Precise software feature.

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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** is unchanged compared to predicate device.

The subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** has been modified to include an optional Artificial Intelligence (AI) imaging MR Reconstruction software feature *SmartSpeed Precise*. Similar as the predicate device, *SmartSpeed Precise* is intended to increase signal-to-noise (SNR), increase sharpness and decrease ringing artefacts in MR images. *SmartSpeed Precise* is combining denoisers from SmartSpeed AI and Precise Image of the predicate device to increase signal-to-noise ratio (SNR) and to allow higher acceleration factors with equal or better image quality. Similar as Precise Image in the predicate device, contains *SmartSpeed Precise* anti ringing filtering to increase sharpness and decrease ringing artefacts in MR images. *SmartSpeed Precise* replaces both SmartSpeed AI and Precise Image in the subject device for 2D Cartesian acquisition. *SmartSpeed Precise* does not impact the intended use of the device, nor does it raise any new questions of safety and effectiveness. The user interface provides operators of the system with a new option for selecting *SmartSpeed Precise* and adjusting the associated level of image noise reduction.

Summary of Non- Clinical Performance Data:

Non-clinical performance testing has been performed on the subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** and demonstrates compliance with following international and FDA-recognized consensus standards:

Recognition Number	Standard Number and Date	Standard Name
12-295	IEC60601-2-33 Ed. 3.2:2010 + Amd 1:2013 + Amd 2:2015	<i>Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis</i>
-	ANSI / AAMI ES60601-1:2005/(R)2012 and A1:2012	<i>Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2006, MOD).</i>
19-36	IEC 60601-1-2:2014 [Including AMD 1:2021]	<i>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic</i>

Recognition Number	Standard Number and Date	Standard Name
		<i>disturbances - Requirements and tests [Including Amendment 1 (2021)]</i>
5-132	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	<i>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability</i>
5-131	ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	<i>Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems [Including Amendment 2 (2021)]</i>
13-79	ANSI AAMI IEC 62304:2006/A1:2016	<i>Medical device software - Software life cycle processes [Including Amendment 1 (2016)]</i>
5-129	ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	<i>Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1</i>
5-125	ANSI AAMI ISO 14971: 2019	<i>Medical devices – Application of risk management to medical devices.</i>

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.

Simulated use validation was executed to obtain evidence of SmartSpeed Precise with respect to its predicate by qualitative review performed by application specialists. Based on the results of the qualitative image review, reproducibility of SmartSpeed Precise in comparison to predicate device reconstruction technique can be considered established. Additionally, a reader evaluation by ABR board certified radiologists was performed, where following properties have been analyzed as part of the comparison: signal-to-noise ratio (SNR), artifact level, sharpness, and contrast-to-noise ratio (CNR). Furthermore, the radiologists have assessed the quality of the visualization of abnormalities and pathologies in case they were present in the images as well as if the images were of sufficient quality for diagnostic purposes. The review evaluation shows that the proposed device is assessed as equivalent for diagnosis and holds significantly better SNR and sharpness compared to the predicate reconstruction technology, also in the presence of (subtle) abnormalities and pathology.

The verification and/or validation test results demonstrate that the subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** are substantially equivalent to the legally marketed predicate device *Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, MR 5300 and MR 7700 R12 MR Systems* (K223458) in terms of safety and effectiveness.

Summary of Clinical Data:

With the subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** and the legally marketed primary predicate device Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, MR 5300 and MR 7700 R12 MR Systems (K223458) 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 subject **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** are substantially equivalent to the legally marketed predicate device *Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, MR 5300 and MR 7700 R12 MR Systems* (K223458) 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 **Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems** meet the acceptance criteria and are adequate for the intended use.