



February 23, 2026

Philips Medical Systems Nederland B.V.
Younkyung Oh
Regulatory Affairs Specialist
Veenpluis 6, 5684 PC, Best
The Netherlands

Re: K253648

Trade/Device Name: Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: Class II

Product Code: LNH, LNI

Dated: January 28, 2026

Received: January 28, 2026

Dear Younkyung Oh:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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 watermark of the letters 'FDA'.

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

Submission Number (if known)

K253648

Device Name

Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades

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.

510(k) Summary

K253648

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

Preparation date: Nov 07, 2025
510(k) Owner: Philips Medical Systems Nederland B.V.
Veenpluis 6, 5684 PC, Best, The Netherlands
Establishment Registration Number: 3003768277

Contact person(s): Younkyung OH (*primary*)
Regulatory Affairs Specialist
Phone: +31 639101812
E-mail: Younkyung.oh@philips.com

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

Device Name: Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR System including Upgrades.

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, BlueSeal, MR 5300 and MR 7700 MR System
510(k) Clearance:	K251397
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

Reference Device	Trade Name:	RTHawk, HeartVista Cardiac Package
	510(k) Clearance:	K212233
	Manufacturer:	HeartVista, Inc
	Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
	Regulation Number:	21 CFR 892.1000
	Review Panel:	90-Radiology
	Device Class:	Class II
	Product Code:	LNH

Device description

The subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** are 60 cm and 70 cm bore 1.5 and 3.0 Tesla (1.5T and 3.0T) Magnetic Resonance Diagnostic Devices.

The following software features are contained in software R13 for the **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades**:

- **SmartHeart** includes an automated cardiac MRI planning feature that uses a CNN-based deep learning model to analyze 3D survey images and suggest standard cardiac imaging planes. The technologist can fully edit these suggestions if needed. The model was trained on de-identified 3D survey images of adult patients from multiple geographies using expert-annotated reference planes. Testing on separate datasets showed performance is within the range expected from trained human operators. This feature supports workflow optimization only and does not perform any image reconstruction or diagnosis.
- **CardiacQuant Perfusion** enables assessment of the myocardial blood flow. It is a dual sequence method to allow for the simultaneous acquisition of both the Arterial Input Function and the perfusion data.
- **Cardiac Motion Correction** enables inline motion correction for the following 2D CMR sequences: Late Gadolinium enhancement (LGE), CardiacQuant Perfusion and T1 mapping. It makes use of Fast Elastic Image Registration between images across time points for the same slice to compensate for motion caused by breathing or differences in cardiac phase.
- **CINE FreeBreathing** is a free-breathing sequence for Cine imaging using respiratory gating to reduce respiratory motion. It allows the user to perform a 2D CINE acquisition in a patient without breath hold commands.
- **4D MR-RT** is a free-breathing scanning method to acquire 3D images for multiple respiratory phases. 4D MR-RT enables radiotherapy planning using MR for moving targets in the abdomen, and breath holds are not mandatory.
- **IRIS** is a Multi-shot SE-EPI diffusion imaging technique which enables higher resolution imaging of the (female) pelvis, prostate and breast.

The introduction of these software features required updates only to the MR system software.

The subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** 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 S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** 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

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 subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** is based on the same principle as the predicate device 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 S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** are unchanged compared to predicate device.

The User Workflow, Scanning and Reconstruction software of the subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** have been modified to include the software features SmartHeart, CardiacQuant Perfusion, Cardiac Motion correction, CINE Free Breathing and 4D MR-RT in software R13, offering an alternative to the current way of user workflow planning, cardiac motion and breath hold scanning and increasing resolution, available on the predicate device.

Summary of Non- Clinical Performance Data:

Non-clinical performance testing was conducted on the subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** and demonstrates compliance with the following international and FDA-recognized consensus standards:

Recognition Number	Standard Number and Date	Standard Name
12-347	IEC 60601-2-33 Edition 4.0 2022-08	<i>Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis</i>
19-46	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	<i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]</i> <i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)</i>
19-36	ANSI AAMI 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 disturbances - Requirements and tests [Including Amendment 1 (2021)]</i>

Recognition Number	Standard Number and Date	Standard Name
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.

The verification and/or validation test results demonstrate that the subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** 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 S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** are substantially equivalent to the legally marketed predicate device *Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems (K251397)* in terms of safety and effectiveness.

Summary of Clinical Data:

With the subject **Ingenia, Ingenia CX, Ingenia Elition S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades**, 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, BlueSeal, MR 5300 and MR 7700 R12.3 MR Systems (K251397)* 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 S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** are substantially equivalent to the legally marketed predicate device *Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition, BlueSeal, MR 5300 and MR 7700 MR Systems* (K251397) 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 S/X, Ingenia Ambition S/X, BlueSeal SE/XE/QE, MR 5300 and MR 7700 MR Systems including Upgrades** meet the acceptance criteria and are adequate for the intended use.