Philips Medical Systems Nederland, B.V.
℅ Jan van de Kerkhof
Sr. Manager Regulatory Affairs
Veenpluis 4-6
Best, 5684PC
NETHERLANDS

March 3, 2022

Re: K213516
Trade/Device Name: Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: January 31, 2022
Received: February 1, 2022

Dear Jan van de Kerkhof:

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

CAPT Patrick Hintz, MSIH, CIH, USPHS
Assistant 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)* K213516

Device Name
Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700

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.**

K213516

**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.

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| **Date Prepared:** | Jan. 20, 2022 | |
| **Manufacturer:** | Philips Medical Systems Nederland B.V.<br>Veenpluis 4-6, 5684 PC, Best, The Netherlands<br>Establishment Registration Number: 3003768277 | |
| **Primary Contact Person:**<br><br><br><br>**Secondary Contact Person** | Jan van de Kerkhof<br>Sr. Manager Regulatory Affairs<br>Phone: +31 613300542<br>E-mail: jan.van.de.kerkhof@philips.com<br><br>Ioana Ulea<br>Senior Regulatory Affairs Specialist<br>Telephone: +31 618345875<br>E-mail: ioana.ulea@philips.com | |
| **Device Name:** | Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei | |
| **Classification:** | Classification name: | Magnetic Resonance Diagnostic Device (MRDD) |
| | Classification Regulation: | 21CFR 892.1000 |
| | Classification Panel: | Radiology |
| | Device Class: | Class II |
| | Primary Product Code: | 90LNH<br>90LNI |
| **Primary Predicate Device:** | Trade name: | Achieva, Intera, Ingenia, Ingenia 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<br>90LNI |

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| **Device Description:** | The proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 are provided on the 60 cm and 70 cm bore 3.0 Tesla (3.0T) Magnetic Resonance Diagnostic Devices.<br><br>This bundled abbreviated 510(k) submission will include modifications of the 3.0T systems, included in the legally marketed predicate device Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020).<br><br>This 510(k) submission will address the following HW and SW modifications for the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 since the clearance of the last submission for each of the systems:<br>• New system MR 7700 which contains modified gradient system compared to Ingenia Elition X<br>• Modified Multi Nuclei option, now available for all 3.0T systems<br><br>This 510(k) submission will also address minor hardware and software enhancements:<br>• Universal Mains Distribution Unit (uMDU)<br>• 3.0T 1H RF Amplifier<br>• Extended Functionality Options<br><br>The proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 are intended to be marketed with the following pulse sequences and coils that were previously cleared by FDA:<br>1. mDIXON (K102344)<br>2. SWIp (K131241)<br>3. mDIXON-Quant (K133526)<br>4. mDIXON XD (K143128)<br>5. O-MAR K143253<br>6. 3D APT (K172920)<br>7. Coils compatible with Ingenia 3.0T, Ingenia 3,0T CX, Ingenia Elition and MR 7700<br><br>The proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 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). |
| **Indications for Use:** | There are no changes to the indications for use statement for the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9.<br><br>*Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device.* |

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| | *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.*<br><br>*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.*<br><br>*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.*<br><br>*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.*<br><br>*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.*<br><br>*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 **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 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.<br><br>The table below lists the main changes between the devices from the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 and devices from the legally marketed predicate device Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020). |

| Device from predicate device | Device from this submission | Main differences |
|---|---|---|
| Ingenia Elition S/X | MR 7700 | Modified gradient system<br>Addition of Distributed Multi Nuclei |
| Ingenia Elition S/X | Ingenia Elition S/X | Addition of Distributed Multi Nuclei |
| Ingenia 3.0T<br>Ingenia 3.0T CX | Ingenia 3.0T<br>Ingenia 3.0T CX | Change in Multi Nuclei functionality |

The following are descriptions of the modified or minor enhanced hardware and software features.

**MR 7700 – Modified Gradient System**

- **Gradient Amplifier** – to achieve the higher maximum amplitude, a new gradient amplifier was needed. The new gradient amplifier has the same principle of operation as the predecessor gradient amplifier found in the legally marketed predicate device, Ingenia Elition X.
- **Gradient Coil** – same as the gradient coil used in the legally marketed predicate device Ingenia Elition X.

**Distributed Multi Nuclei**

The Multi Nuclei function is available as a commercial option on the predicate devices Ingenia 3.0T and Ingenia 3.0T CX from the legally marketed predicate device Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020).

Currently the legally marketed predicate devices, Ingenia 3.0T and Ingenia 3.0T CX, have the Multi Nuclei option $^{31}$P supported as fully integrated. The modified Multi Nuclei option consists of additional nuclei to the MR system to transmit and receive on frequencies other than the frequency used for phosphor (31P). For the Ingenia 3.0T and Ingenia 3.0T CX this gives the possibility to create Spectra and Images for additional nuclei $^{13}$C, $^{23}$Na, next to being technical prepared for other nuclei. For Ingenia Elition S/X and the MR 7700 the modified Multi Nuclei option is newly introduced.

**Universal Mains Distribution Unit (uMDU)**

The universal Mains Distribution Unit (uMDU) is a unit that connects to the hospital mains inlet. The unit consists of circuit breakers / switches for the different parts of the MRI system. The switch for the gradient amplifier cabinet is changed to a higher rated switch due to the increased input power requirement of the new gradient amplifier for the proposed **MR 7700**. The modified uMDU is used in Ingenia Elition S, Ingenia Elition X and MR 7700 of the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9.

**3.0T 1H RF Amplifier**

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| | The 1H RF Amplifier is a unit that delivers high power RF to the Transmit/Receive coils (either the system Body coil or local Transmit/Receive coils. A new 3.0T 1H RF Amplifier has been designed with same specifications and characteristics as the 3.0T 1H RF Amplifier which is part of the 3.0T devices of the legally marketed Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020).<br><br>**Extended Functionality Options**<br>Minor software enhancements regarding extended functionality options. These minor software enhancements are related to parameter extensions for advanced users, and do not pose any risk, nor have impact on safety and efficacy.ased on the information provided above, the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 do not raise different questions of safety and effectiveness compared to the legally marketed predicate device Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition, and Ingenia Ambition MR Systems R5.7 (K193215, 04/10/2020), therefore demonstrating substantial equivalence. |
| **Summary of Non-Clinical Performance Data:** | Philips Medical Systems Nederland B.V. declares that the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 are in compliance with all applicable requirements of the following international and FDA recognized consensus standards:<br><br>**Ingenia, Ingenia CX, Ingenia Elition, Ingenia Ambition**<br><br>• IEC60601-1 Edition 3<br>• IEC60601-1-2 Edition 4<br>• IEC60601-1-6 Edition 3<br>• IEC62366-1 Edition 1<br>• IEC60601-1-8 Edition 2<br>• IEC60601-2-33 Edition 3<br>• IEC 62304 Edition 1<br>• NEMA MS-1 2008<br>• NEMA MS-4 2010<br>• NEMA MS-8 2008<br>• NEMA PS 3.1-PS 3.20<br>• ISO 14971 Edition 2<br>• Device specific guidance document, entitled “Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices” (issued November 18, 2016)<br>• Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005)<br>• Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 02 2014)<br>• Guidance for Industry and FDA Staff – Applying Human Factors and Usability Engineering to Medical Devices (issued February 3, 2016) |

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| | • 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 September 04, 2020<br>• Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (issued July 11, 2016)<br>• Guidance for Industry and FDA Staff –*Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices* (issued September 6, 2017)<br><br>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.<br><br>Test results demonstrate that the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 meet the acceptance criteria and are adequate for its 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.<br>Therefore, the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 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 safety and effectiveness. |
| **Summary of Clinical Data:** | The proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 did not require a clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing. |
| **Substantial Equivalence:**<br><br>**Conclusion:** | The proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 and the legally marketed predicate 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:<br>• Providing cross-sectional images based on the magnetic resonance phenomenon<br>• Interpretation of the images is the responsibility of trained physicians<br>• Images can be used for interventional and treatment planning purposes<br><br>The proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 are substantially equivalent to the legally marketed predicate 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.<br><br>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. |

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| | The results of these tests demonstrate that the proposed **Ingenia 3.0T, Ingenia 3.0T CX, Ingenia Elition and MR 7700 with Distributed Multi Nuclei** R5.9 meet the acceptance criteria and are adequate for their intended use. |