Philips Medical Systems Nederland B.V.
℅ Ioana Ulea
Senior Regulatory Affairs Specialist
Veenpluis 6
Best, 5684 PC
Netherlands

August 2nd, 2023

Re: K232030
Trade/Device Name: Ingenia Elition R5.7.1 SP4 MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: July 6, 2023
Received: July 7, 2023

Dear Ioana Ulea:

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,

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

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)*
K232030

Device Name
Ingenia Elition R5.7.1 SP4 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.

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:	July 06, 2023	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC, Best, The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person: **Secondary Contact Person**	Ioana Ulea Senior Regulatory Affairs Specialist Phone: +31 618345875 E-mail: ioana.ulea@philips.com Jan van de Kerkhof Associate Director Regulatory Affairs Phone: +31 613300542 E-mail: jan.van.de.kerkhof@philips.com	
Device Name:	**Ingenia Elition R5.7.1 SP4 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, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K193215, 04/10/2020
	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:	This Special 510(k) submission will include modifications of the proposed **Ingenia Elition R5.7.1 SP4 MR Systems** as compared to Philips legally marketed predicate device Ingenia Elition of the 510(k) submission *Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems* (K193215, 04/10/2020).

	In this 510(k) submission, Philips Medical Systems Nederland B.V. will be addressing the following minor software enhancements for the proposed **Ingenia Elition R5.7.1 SP4 MR Systems**: 1. Introduction of a persistence latch which will prevent the currently available Interlock of SmokeDetector to be reset by customer, which is against the current labeling (abnormal use). 2. The UI (User Interface) and IfU (Instructions for Use) are also updated to provide clear instructions for the user in case the currently available SmokeDetector Alarm Interlock is activated and to further clarify current instructions to prevent powercycling the system (abnormal use). 3. SW Compatibility with the PD-Break Heat Detector Identical to the predicate device, the proposed **Ingenia Elition R5.7.1 SP4 MR Systems** is 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 (identical to the predicate devices)
Indications for Use:	There are no changes to the indications for use statement, provided below, of the proposed **Ingenia Elition R5.7.1 SP4 MR Systems** when compared to the predicate device Ingenia Elition of the 510(k) submission *Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems* (K193215, 04/10/2020)*:* *"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.*

<table>
<tr><td></td><td>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".</td></tr>
<tr><td>Design Features/ Fundamental Scientific Technology:</td><td>Same as the predicate device, the proposed Ingenia Elition R5.7.1 SP4 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 Ingenia Elition R5.7.1 SP4 MR Systems are fundamentally the same as those used in the legally marketed predicate device Ingenia Elition of the 510(k) submission Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems (K193215, 04/10/2020).</td></tr>
<tr><td>Summary of Non-Clinical Performance Data:</td><td>Identical to the predicate device, the proposed Ingenia Elition R5.7.1 SP4 MR Systems are in compliance with the following international and FDA-recognized consensus standards:
<table>
<tr><th>No.</th><th>Recognition Number</th><th>Standard Number and Date</th><th>Standard Name</th></tr>
<tr><td>1</td><td>12-295</td><td>IEC60601-2-33 Ed. 3.2:2010 + Amd 1:2013 + Amd 2:2015</td><td>Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis</td></tr>
<tr><td>2</td><td>19-4</td><td>ANSI / AAMI ES60601-1:2005/(R)2012 and A1:2012</td><td>Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2006, MOD).</td></tr>
</table></td></tr>
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	3	19-8	IEC60601-1-2 Ed. 4.0:2014	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*
	4	5-89	IEC 60601-1-6 Ed. 3.1:2010 + Amd 1:2013	*Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability*
	5	5-76	IEC 60601-1-8 Ed. 2.1:2006 + Amd 1:2012 (Ed.2.1)	*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*
	6	5-125	ISO 14971 Third Edition 2019	*Medical devices – Application of risk management to medical devices.*
	7	5-114	IEC 62366-1 Ed. 1.0:2015	*Medical devices – Part 1: Application of usability engineering to medical devices*
	8	13-79	IEC 62304 Ed. 1.1:2015	*Medical device software – Software life cycle processes.*
	Non-Clinical verification tests were deemed necessary with regards to the requirement specifications and the risk management results. The verification test results demonstrate that the proposed **Ingenia Elition R5.7.1 SP4 MR Systems** meet the acceptance criteria and are adequate for the intended use. The validation testing performed with the predicate device remain valid for the changes introduced with the proposed device **Ingenia Elition R5.7.1 SP4 MR Systems.** 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 **Ingenia Elition R5.7.1 SP4 MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia Elition of the 510(k) submission *Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems* (K193215, 04/10/2020) in terms of safety and effectiveness.			
Summary of Clinical Data:	The proposed **Ingenia Elition R5.7.1 SP4 MR Systems** did not introduce any modification to the indication for use or technological characteristics relative to the predicate devices that would require clinical testing.			
Substantial Equivalence:	The proposed **Ingenia Elition R5.7.1 SP4 MR Systems** and the legally marketed predicate device Ingenia Elition of the 510(k) submission *Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition*			

Conclusion:	*MR Systems* (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 **Ingenia Elition R5.7.1 SP4 MR Systems** are substantially equivalent to the legally marketed predicate device Ingenia Elition of the 510(k) submission *Achieva, Intera, Ingenia, Ingenia CX, Ingenia Elition and Ingenia Ambition MR Systems* (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 tests and compliance 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 **Ingenia Elition R5.7.1 SP4 MR Systems** meet the acceptance criteria and are adequate for the intended use.