Philips Medical Systems Nederland B.V.
Henrie Daniels
Regulatory Affairs Specialist
Veenpluis 4-6
Best, 5684PC Nl

March 6, 2018

Re: K173356
Trade/Device Name: Ingenia Elition S and Ingenia Elition X R5.4
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: January 30, 2018
Received: February 2, 2018

Dear Henrie Daniels:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173356

Device Name
Ingenia Elition S and Ingenia Elition X R5.4

Indications for Use *(Describe)*

This system is a Magnetic Resonance Medical Electrical Systems indicated for use as a diagnostic device. The system can produce cross-sectional images, spectroscopic images and/or spectra in any orientation of the internal structure of the head, body or extremities.

Magnetic Resonance images represent 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, and the MR scan technique applied. The image acquisition process can be synchronized 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 the 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. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Ingenia Elition S and Ingenia Elition X R5.4

Section 5

510(k) Summary

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:	October 20, 2017	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6, 5684 PC, Best, The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person: **Secondary Contact Person**	Jan van de Kerkhof Sr. Manager Regulatory Affairs Phone: +31 613300542 E-mail: jan.van.de.kerkhof@philips.com Henrie Daniels Regulatory Affairs Specialist Telephone: +31 643837374 E-mail: henrie.daniels@philips.com	
Device Name:	Ingenia Elition S and Ingenia Elition X R5.4	
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:	Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K163116
	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:	The proposed **Ingenia Elition S and Ingenia Elition X R5.4** with new gradient system/specifications are modifications of the 70 cm Ingenia 3.0T system, included in the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017). The systems and control software are substantially equivalent to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017). Hereafter **Ingenia Elition S and Ingenia Elition X R5.4** will be used to indicate the proposed device **Ingenia Elition S and Ingenia Elition X R5.4** with new gradient system/specifications The proposed **Ingenia Elition S and Ingenia Elition X R5.4** also includes minor software changes since the clearance of the legally marketed predicate device, Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017). The following modifications are covered compared to legally marketed predicate device: 1. Upgrade of SW platform to Windows 10 and PSC 6.1 (to be compatible with Windows 10); 2. PerformanceBridge Protocol Manager Release 1.0; 3. Introduction of new gradient system hardware with new gradient specifications; 4. Introduction of new product name and covers. The proposed **Ingenia Elition S and Ingenia Elition X R5.4** are intended to be marketed with the following pulse sequences and coils that were 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. MultiBand SENSE K143606 8. Ingenia Coils See Appendix 004

Indications for Use:	This system is a Magnetic Resonance Medical Electrical Systems indicated for use as a diagnostic device. The system can produce cross-sectional images, spectroscopic images and/or spectra in any orientation of the internal structure of the head, body or extremities. Magnetic Resonance images represent 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, and the MR scan technique applied. The image acquisition process can be synchronized 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 the 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. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent. 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 proposed **Ingenia Elition S and Ingenia Elition X R5.4** 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, receive coils and patient support) of the proposed **Ingenia Elition S and Ingenia Elition X R5.4** are identical to those used in the legally marketed predicate device, Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017), except for the transmit body coil and the gradient coil, which have been changed to adapt to the changed voltage levels of the gradient amplifier. Based on the information provided above, the proposed **Ingenia Elition S and Ingenia Elition X R5.4** does not raise different questions of safety and effectiveness compared to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017).

Summary of Non-Clinical Performance Data:	The proposed **Ingenia Elition S and Ingenia Elition X R5.4** comply with the following international and FDA-recognized consensus standards: • IEC60601-1 Edition 3 • IEC60601-1-2 Edition 3 • IEC60601-1-6 Edition 3 • IEC62366 Edition 1 • IEC60601-1-8 Edition 2 • IEC60601-2-33 Edition 3 • IEC 62304 Edition 1 • NEMA MS-1 2008 • NEMA MS-4 2010 • NEMA MS-8 2008 • NEMA PS 3.1-PS 3.20 • ISO 14971 Edition 2 • Device specific guidance document, entitled “Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 18, 2016” • Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 11, 2005) • Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices 9 issued February 3, 2016) • Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued October 2, 2014 • 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 June 16, 2016) • Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (issued July 11, 2016) 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. The verification and/or validation test results demonstrate that the proposed **Ingenia Elition S and Ingenia Elition X R5.4**:

	• Complies with the aforementioned international and FDA recognized consensus standards and Device specific guidance document, entitled "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 18, 2016" • Meets the acceptance criteria and is adequate for its intended use. Therefore, the proposed **Ingenia Elition S and Ingenia Elition X R5.4** are substantially equivalent to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **Ingenia Elition S and Ingenia Elition X R5.4** did not require a clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.
Substantial Equivalence: **Conclusion:**	The proposed **Ingenia Elition S and Ingenia Elition X R5.4** and the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017) 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 S and Ingenia Elition X R5.4** are substantially equivalent to the legally marketed predicate device Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, 01/06/2017) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was 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 proposed **Ingenia Elition S and Ingenia Elition X R5.4** meet the acceptance criteria and is adequate for its intended use.