June 15, 2018

Philips Healthcare (Suzhou) Co., Ltd.
℅ Jacky Shi
Senior Regulatory Engineer
No. 258, Zhongyuan Road
Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K173507
Trade/Device Name: Prodiva 1.5T CX and Prodiva 1.5T CS R5.4
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, and MOS
Dated: May 30, 2018
Received: June 6, 2018

Dear Jacky Shi:

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 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 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)*

k173507

Device Name
Prodiva 1.5T CX and Prodiva 1.5T CS R5.4

Indications for Use *(Describe)*

This system is a Magnetic Resonance Medical Electrical System 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."

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:	November 8, 2017	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, Zhongyuan Road, Suzhou Industrial Park, Suzhou Jiangsu, CHINA, 215024 Establishment Registration Number: 3009529630	
Primary Contact Person: **Secondary Contact Person**	Jacky Shi Senior Regulatory Engineer Phone: +86 512-67336881 E-mail: Jacky.Shi@philips.com Gordon Shu Senior Regulatory Manager Phone: +86-512-67336804 E-mail: Gordon.Shu@philips.com	
Device Name:	Prodiva 1.5T CX and Prodiva 1.5T CS 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 90MOS
Primary Predicate Device: System	Trade name:	Ingenia 1.5T CX R5.3
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K162931
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic resonance diagnostic device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	90LNH 90LNI
Reference Predicate Device: Coils	Trade name:	dS Anterior, dS Base, dS Head-neck, dS Head, Flex (S, M L)
	Manufacturer:	PHILIPS MEDICAL SYSTEMS 3545 s w 47th avenue Gainesville, FL 32608 -1099
	510(k) Clearance:	K123492
	Classification Regulation:	21CFR 892.1000
	Classification name:	Coil, Magnetic Resonance, Specialty
	Classification Panel:	Radiology

	Device class	Class II
	Product Code:	90MOS
Device Description:	The proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** are 60 cm bore 1.5 Tesla (1.5T) magnetic resonance diagnostic devices. The systems and control software are substantially equivalent to the currently marketed predicate device Ingenia 1.5T CX R5.3 (K162931, 01/06/2017). The system includes a new 1.5T magnet, new set of RF receive coils, new patient support, new in-house Gradient system and RF transmit system and adapted RF receive system which is substantially equivalent to the currently marketed predicate device Ingenia 1.5T CX R5.3.	

Indications for Use:	*This system is a Magnetic Resonance Medical Electrical System 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.*

Fundamental Scientific Technology:	The proposed **Prodiva 1.5T CX and Prodiva 1.5T CS 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, transmit body coil, gradient coil, receive coils and patient support) of the proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** substantially equivalent to the currently marketed predicate device Ingenia 1.5T CX R5.3 (K162931, 01/06/2017). Based on the information provided above, the proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** does not raise different questions of safety and effectiveness compare to the currently marketed predicate device Ingenia 1.5T CX R5.3 (K162931, 01/06/2017).

Summary of Non-Clinical Performance Data:	The proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** comply with the following international and FDA-recognized consensus standards: • IEC 60601-2-33 Edition 3.1: 2013 Medical Electrical Equipment - Part 2-33: Particular Requirements For The Basic Safety And Essential Performance Of Magnetic Resonance Equipment For Medical Diagnosis. FDA/CDRH recognition number 12-271 • AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD). FDA/CDRH recognition number 19-4 • IEC 60601-1-2 Edition 3: 2007-03 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility -Requirements And Tests FDA/CDRH recognition number 19-1 • IEC 60601-1-6 Edition 3.1: 2013-10 Medical Electrical Equipment -- Part 1-6: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Usability FDA/CDRH recognition number 5-89 • IEC 62366 Edition 1.1: 2014-01 Medical devices – Application of usability engineering to medical devices FDA/CDRH recognition number 5-87 • IEC 62304 Edition 1.1: 2015 Medical device software – Software life cycle processes. FDA recognition number 13-79 • ISO14971 Edition 2: 2007-03-01 Medical devices – Application of risk management to medical devices. FDA/CDRH recognition number 5-40 • NEMA MS 1-2008 Determination of Signal-To-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging FDA/CDRH recognition number 12-188 • NEMA MS 2-2008 (R2014) Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images FDA/CDRH recognition number 12-196

	• NEMA MS 3-2008 (R2014) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images FDA/CDRH recognition number 12-187 • NEMA MS 4-2010 Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices. FDA/CDRH recognition number 12-232 • NEMA MS 5-2009 Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging FDA/CDRH recognition number 12-231 • NEMA MS 6-2008 (R2014) Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI) FDA/CDRH recognition number 12-195 • NEMA MS 8-2008 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems FDA/CDRH recognition number 12-192 • NEMA MS 9-2008 (R2014) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI) FDA/CDRH recognition number 12-288 • NEMA MS 12-2016 Quantification and Mapping of Geometric Distortion for Special Applications FDA/CDRH recognition number 12-306 • NEMA PS 3.1-PS 3.20 - [DICOM] Digital Imaging and Communications in Medicine, Parts 1 - 20 FDA recognition number 12-300 • Device specific guidance document, entitled Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (issued 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 — Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014)

	• Guidance for Industry and FDA Staff— Applying Human Factors and Usability Engineering to Optimize Medical Device Design (issued Feb. 03, 2016) • 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 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 validation test results, combined with sample clinical images demonstrate that the proposed **Prodiva 1.5T CX and Prodiva 1.5T CS 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 **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** are substantially equivalent to the currently marketed predicate device Ingenia 1.5T CX R5.3 (K162931, 01/06/2017) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** did not require clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing. Clinical sample images were provided to support the ability of proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** to generate diagnostic quality images.

Substantial Equivalence Conclusion:	The proposed **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** and the currently marketed predicate device Ingenia 1.5T CX R5.3 (K162931, 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 **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** are substantially equivalent to the currently marketed predicate device Ingenia 1.5T CX R5.3 (K162931, 01/06/2017) in terms of design features, fundamental scientific technology, indications for use, and safety & 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 **Prodiva 1.5T CX and Prodiva 1.5T CS R5.4** meet the acceptance criteria and is adequate for its intended use.