Philips Medical Systems Nederland B.V.
% Susan Quick
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland) Inc.
595 Miner Rd
CLEVELAND OH 44143

January 22, 2018

Re: K172920
Trade/Device Name: 3d Apt
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI
Dated: December 22, 2017
Received: December 26, 2017

Dear Susan Quick:

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,

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)*
K172920

Device Name
3D APT

Indications for Use *(Describe)*

Amide Proton Transfer weighted imaging (3D APT) is a software option intended for use on Ingenia 3.0T and Ingenia 3.0T CX MR Systems. 3D APT is indicated for use in magnetic resonance imaging of the brain. 3D APT consists of an acquisition and reconstruction technique employing frequency-selective magnetization transfer effects to derive images reflecting the spatial distribution of amide protons, and thereby protein density. 3D APT images may assist a trained physician in diagnosis and therapy planning. APTW can be combined with multi-coil acceleration approaches (SENSE).

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.

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3D APT

Section 005

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:	September 30, 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**	Susan Quick Regulatory Affairs Specialist Phone: (440) 483-2291 E-mail: susan.quick@philips.com Jan van de Kerkhof Sr Manager Regulatory Affairs Phone: +31 6 13300542 E-mail: jan.van.de.kerkhof@philips.com	
Device Name:	Amide Proton Transfer weighted MRI (3D APT)	
Classification:	Classification name:	Magnetic Resonance Diagnostic device (MRDD)
	Classification Regulation:	21CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	LNH, LNI
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, January 6, 2017
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	LNH, LNI
	Product Code:	LNH, LNI

Device Description:	**3D Amide Proton Transfer (3D APT)** is an extension of off-resonance magnetization transfer imaging. 3D APT images display a spatial distribution of amide protons. The RF-shimmed saturation is generated by alternating excitation from the 2 channels of the MultiTransmit system. 3D APT images are obtained by subtracting the saturated image intensity at the 2 mirrored frequency offsets relative to the water frequency (±3.5 ppm). Parameters are optimized to null the difference signal for normal brain tissue.
Indications for Use:	**3D Amide Proton Transfer weighted MRI (3D APT)** is a software feature intended for use on Ingenia 3.0T (70cm) and Ingenia 3.0T CX (60cm) MR Systems. It's indicated for use in magnetic resonance imaging of the brain. Amide Proton Transfer weighted imaging (3D APT) is a software option intended for use on Ingenia 3.0T and Ingenia 3.0T CX MR Systems. 3D APT is indicated for use in magnetic resonance imaging of the brain. 3D APT consists of an acquisition and reconstruction technique employing frequency-selective magnetization transfer effects to derive images reflecting the spatial distribution of amide protons, and thereby protein density. 3D APT images may assist a trained physician in diagnosis and therapy planning. APTW can be combined with multi-coil acceleration approaches (SENSE).
Design Features and Fundamental Scientific Technology:	**3D Amide Proton Transfer (3D APT)** is an MR imaging technology where saturation of the water signal using the magnetization transfer effect generates the contrast. Protons bound to macromolecules, specifically amide protons, exchange with the free water pool. Selective narrow-band excitation at the amide proton resonance frequency is used to detect signal differences exclusively associated with the amide protons. This is achieved by a controlled, frequency-selective RF irradiation to saturate protons resonating at +3.5 ppm (the amide proton resonance frequency), and comparing the resulting signal level to that observed when irradiating at –3.5 ppm. The feature consists of: • Frequency selective saturation RF pulses (1-2 s duration), alternating between the two channels of the MultiTransmit RF system, at multiple offset frequencies • 3D DIXON TSE readout • Signal difference calculation between +3.5 ppm and –3.5 ppm to derive the APTw image • B0 inhomogeneity correction embedded into the APTw calculation • Color scale (rainbow) to display APTw signals between –5% and +5%.

Summary of Non-Clinical Performance Data:	The proposed 3D **Amide Proton Transfer (3D APT)** complies with the following international and FDA-recognized consensus standards: • IEC 62304 Medical device software - Software life cycle processes • ISO 14971 Application of risk management to medical devices • Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 18, 2016" • 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 Non-Clinical verification and validation test results, combined with the sample images, demonstrate that the proposed 3D APT: • Complies with the aforementioned international and FDA-recognized consensus standards and device specific guidance document • Meets the acceptance criteria and is adequate for its intended use. Therefore, the proposed **3D Amide Proton Transfer (3D APT)** is substantially equivalent to the legally marketed primary predicate device, Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, January 6, 2017) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **3D Amide Proton Transfer (3D APT)** did not require a clinical study since substantial equivalence to the primary predicate device was demonstrated with the following attributes: • Design features; • Indication for use; • Fundamental scientific technology; • Non-clinical performance testing; and • Safety and effectiveness.

Substantial Equivalence	The proposed **3D Amide Proton Transfer (3D APT)** is substantially equivalent to the Magnetization Transfer functionality (MTC and MTR) of the legally marketed primary predicate device, Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, January 6, 2017) and has the same primary indications for use with respect to the following: • Software feature intended for use on the Ingenia 3.0T (70cm) and Ingenia 3.0T CX (60cm) MR Systems • Use in magnetic resonance imaging of the brain • Consists of an image acquisition and reconstruction technique with B0 correction and difference signal determination
Conclusion:	The proposed **3D Amide Proton Transfer (3D APT)** is substantially equivalent to the legally marketed primary predicate device, Ingenia 1.5T, Ingenia 1.5T S and Ingenia 3.0T R5.3 (K163116, January 6, 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 **3D Amide Proton Transfer (3D APT)** meets the acceptance criteria and is adequate for its intended use.