DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 30, 2016

Philips Medical Systems Nederland B.V.
% Susan Quick
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland) Inc.
595 Miner Rd
CLEVELAND, OH 44094

Re: K162940
Trade/Device Name: MultiBand SENSE
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: October 20, 2016
Received: October 21, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162940

Device Name

MultiBand SENSE

Indications for Use *(Describe)*

MultiBand SENSE is a software option intended for use on Ingenia 3.0T and Ingenia 3.0T CX MR Systems. It's indicated for use in magnetic resonance imaging of the brain for BOLD fMRI and for diffusion weighted imaging. MultiBand SENSE consists of an acquisition and reconstruction technique allowing simultaneous excitation of multiple volumes to accelerate imaging acquisition times, or increasing coverage or number of diffusion directions without increasing scan time.

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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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 14, 2016	
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 Regulatory Affairs Manager Phone: +31 6 13300542 E-mail: jan.van.de.kerkhof@philips.com Susan Quick Regulatory Affairs Specialist Phone: (440) 483-2291 E-mail: susan.quick@philips.com	
Device Name:	MultiBand SENSE (MBSENSE)	
Classification:	Classification name:	Magnetic Resonance Diagnostic device (MRDD)
	Classification Regulation:	21CFR 892.1000
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	LNH
Primary Predicate Device:	Trade name:	MultiBand SENSE
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K143606, May 08, 2015
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	LNH
Reference Predicate Device:	Trade name:	ACHIEVA R4 1.5T AND ACHIEVA R4 3.0T
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K110151, March 22, 2011
	Classification Regulation:	21CFR 892.1000
	Classification name:	Magnetic Resonance Diagnostic Device (MRDD)
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	LNH

Device Description:	The **Multiband SENSE** feature enables simultaneous excitation and acquisition of multiple volumes for spin echo and gradient echo MR sequences for the purpose of speeding up acquisition times or increasing coverage or resolution without increasing scan time. The simultaneous volume excitation is achieved using a multiband RF pulse. The image unfolding of the simultaneously acquired volumes is done using the SENSE algorithm. The image unfolding is improved by introducing a shift in k-space in the phase direction which is dependent on the volume spatial location, resulting in a spatial shift of the aliased pixels. Artifacts related to mismatch between SENSE reference scan and the clinical scan are minimized using information from a previously acquired B_0 map. The **MultiBand SENSE** feature is available on Ingenia 3.0T and Ingenia 3.0T CX systems, and is compatible with the 32 channel head coil.
Indications for Use:	MultiBand SENSE is a software option intended for use on Ingenia 3.0T and Ingenia 3.0T CX MR Systems. It's indicated for use in magnetic resonance imaging of the brain for BOLD fMRI and for diffusion weighted imaging. MultiBand SENSE consists of an acquisition and reconstruction technique allowing simultaneous excitation of multiple volumes to accelerate imaging acquisition times, or increasing coverage or number of diffusion directions without increasing scan time.
Fundamental Scientific Technology:	The **MultiBand SENSE** feature enables simultaneous excitation and acquisition of multiple volumes or slices for the purpose of speeding up acquisition times or increasing coverage or resolution at constant scan time. The simultaneous excitation is done using a multi-band radio-frequency pulse. The unfolding of the simultaneously acquired volumes is done using the SENSE algorithm. The unfolding process (solving the linear equation of the SENSE algorithm) is improved by introducing a linear phase over k-space in the volume direction resulting in a spatial shift of the aliased pixels. The phase shift is applied by additional blip-gradients in the slice direction or switching between different RF pulses, and compensated for in reconstruction by a translation of the coil sensitivity data before the SENSE unfolding. The feature consists of: • Modulated RF pulses exciting 2 or more spatial slice locations • Blip-gradients to introduce a phase shift on slices for improved unfolding • Shifting coil sensitivities in reconstruction to correct for linear phase shift. • Automatic use of B_0 inhomogeneity information to correct geometric distortions in the SENSE calculation

Summary of Non-Clinical Performance Data:	The proposed **MultiBand SENSE** 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 (2012) • Device specific guidance document, entitled "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices – November 14, 1998" • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices 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 demonstrate that the proposed **MultiBand SENSE**: • 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 **MultiBand SENSE** is substantially equivalent to the primary predicate device, MultiBand SENSE (K143606, 05/08/2015) and the reference predicate device Achieva R4 1.5T and Achieva R4 3.0T (K110151, 03/22/2011) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed **MultiBand SENSE** 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 Conclusion:	The proposed **MultiBand SENSE** and the primary predicate device, MultiBand SENSE (K143606, 05/08/2015) and reference predicate device Achieva R4 1.5T and Achieva R4 3.0T (K110151, 03/22/2011) have the same primary indications for use with respect to the following: • Software option intended for use on the Ingenia 3.0T and Ingenia 3.0T CX MR Systems • Use in magnetic resonance imaging of the brain for BOLD fMRI • Consists of an acquisition and reconstruction technique allowing simultaneous excitation of multiple volumes to accelerate imaging acquisition times or increasing coverage or resolution without increasing scan time The proposed **MultiBand SENSE** is substantially equivalent to the primary predicate device, MultiBand SENSE (K143606, 05/08/2015) and reference predicate device Achieva R4 1.5T and Achieva R4 3.0T (K110151, 03/22/2011) 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 **MultiBand SENSE** met the acceptance criteria and is adequate for its intended use.