DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 9, 2015

Philips Medical Systems, Nederland B.V.
% Ms. Susan Quick
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K143253
Trade/Device Name: O-MAR
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 23, 2015
Received: March 24, 2015

Dear Ms. 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 yours,

for

Robert Ochs, Ph.D.
Acting 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)*
K143253

Device Name
O-MAR

Indications for Use *(Describe)*

O-MAR is a combination of an acquisition technique and post-processing software intended for use on Achieva and Ingenia, 1.5T & 3T MR Systems. O-MAR is suitable for use on all patients with passive MR Conditional orthopedics implants that are scanned according to the conditions of safe use for the specific MR Conditional implant being scanned. In addition O-MAR is suitable for use on patients without implants that are cleared for MR exams. O-MAR helps reduce artifacts caused by presence of metal in both in-plane and through-plane dimensions compared to conventional MR imaging techniques. Thus O-MAR improves visualization of more tissue in the vicinity of MR Conditional orthopedic implants. When interpreted by a trained physician, images generated by O-MAR provide information that can be useful in determining a diagnosis.

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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PHILIPS

Philips Medical Systems Nederland B.V.

510(k) Summary

O-MAR

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. General Information
21 CFR 807.92 (a)(1), (2)

Company Name:	Philips Medical Systems Nederland B.V.
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Registration No.:	3003768277
Contact Person:	Susan Quick 595 Miner Rd Cleveland, Oh 44143 Tel: (440)-483-2291 Fax: (440)-483-4799 E-mail: susan.quick@philips.com
Prepared (date):	2014 November XX
Trade Name of Device:	O-MAR
Classification:	Class II
Regulatory Section:	Magnetic Resonance Diagnostic Device. 892.1000
Product Code:	90LNH

21 CFR 807.92(a)(3):Legally marketed predicate device to which substantial equivalence is claimed:

1. Primary Predicate Device: MAVRIC SL
   Manufacturer: GE Healthcare
   Predicate Device k#: K113394

21 CFR 807.92(a)(4): Description of the device that is the subject of this premarket notification:

Summary of functions of the device and its major components

The O-MAR feature has two components. The SEMAC+VAT feature and the MARS+VAT feature. SEMAC+VAT is a Turbo Spin Echo method in combination with VAT (View Angle Tilting) and with multiple z-encodings per excited slice (aka SEMAC) to reduce in-plane and through-plane distortions caused by magnetic field inhomogeneities. MARS is high band width TSE. MARS+VAT can also be referred to as high band width TSE+VAT.

A difference between SEMAC+VAT and MARS+VAT is that SEMAC+VAT also provides through plane as well as in plane artifact reduction, MARS+VAT only provides in plane artifact reduction. SEMAC uses a slice selective TSE acquisition. Multiple z-encodings per excited slice are used to recover off-resonant signal caused by magnetic field inhomogeneities. The output image for each slice represents a combination of the signal acquired at different off-resonant frequencies. SEMAC takes care of corrections in the through-slice direction. The VAT (View angle tilting) technique is used to reduce in-plane distortions. For this, the gradient applied during slice selection is reapplied during the signal readout.

The feature consists of:

- Specific imaging sequence based on multiple overlapping 3D volumes, where the 3D volume aims at capturing the different frequencies caused by the distortion.
- A new calculation function to combine different frequency MR signals into a single undistorted slice.
- A TSE-based SENSE reference scan, which is more robust towards the metal distortions than standard FFE reference scans
- VAT gradient control in sequences.
- VAT is combined with SEMAC or MARS. MARS (Metal artifact reduction sequence) is a slice selective high bandwidth TSE sequence which can be achieved with standard settings of the TSE sequences.

O-MAR is supported on the following systems:

- 3.0T Ingenia
- 3.0T Achieva
- 1.5T Ingenia
- 1.5T Achieva

The functionality is supported on all available gradient performance levels. Optimized protocols will be provided for the different performance points. O-MAR is supported on the centralized data acquisition systems of the Achieva systems as well as the digitally networked data acquisition system of the Ingenia systems. The data acquisition system is fully transparent to the O-MAR pulse sequences reconstructions.

21 CFR 807.92(a)(5): Intended Use

O-MAR is a combination of an acquisition technique and post-processing software intended for use on Achieva and Ingenia, 1.5T & 3T MR Systems. O-MAR is suitable for use on all patients with passive MR Conditional orthopedics implants that are scanned according to the conditions of safe use for the specific MR Conditional implant being scanned. In addition O-MAR is suitable for use on patients without implants that are cleared for MR exams. O-MAR helps reduce artifacts caused by presence of metal in both in-plane and through-plane dimensions compared to conventional MR imaging techniques. Thus O-MAR improves visualization of more tissue in the vicinity of MR Conditional orthopedic implants. When interpreted by a trained physician, images generated by O-MAR provide information that can be useful in determining a diagnosis.

21 CFR 807.92(a)(6): Technological Characteristics:

The main functional units in the software are:

- Methods (acquisition of MR signals by means of MR pulse sequences)
- Reconstruction (transforming the MR signals to images)
- Patient Administration (storing of the images in the database and providing access)
- Viewing (display of images)

The technical impact of the feature O-MAR comprises:

- Methods: Modify an existing 2D sequence to acquire multiple 3D volumes for near metal imaging, within the cleared limits provided by the basic MR system. Add an additional gradient during readout for VAT. The TSE SENSE reference scan and the MARS protocol are achieved with cleared settings within the existing capabilities of the MRI system.
- Reconstruction: Add a new calculation function that combines the frequency shifted slices into distortion corrected slices.

No off-the-shelf software is used for the feature near metal imaging. The off-the-shelf software used in the basic MR system is cleared. O-MAR is not designed to be connected to an external network.MR system is cleared.

O-MAR does not require any change of the hardware platform. The extension introduced by O-MAR, are in methods pulse sequence code, and in reconstruction for the new calculation. Those run on the host computer:

Computer characteristics:

- Manufacturer: HP; Model: Z420; Processor clock: 3.5 GHz; RAM: 64 GB RAM; Processors: six core with hyper threading
- Operating system: Windows 7, 64 bits

Changes to operator workflow for O-MAR are:

- Protocol selection: The operator selects an ExamCard with O-MAR protocols
- Planscan phase: Optionally the operator may want to change the SEMAC factor.

All other steps are not changed. The generated image types can be viewed, post-processed, printed and archived as any other image type.

21 CFR 807.92(b)(1): Brief discussion of nonclinical tests submitted, referenced or relied on in this premarket notification:

O-MAR has been verified to function with the Achieva and Ingenia 1.5T and 3.0T MR systems. The verification testing showed the examcards could be loaded, a Sense reference scan could be added and all scans ran properly. It was also verified that the IFU contained the appropriate warning messages for persons with metallic implants.
The conclusion from Verification Report DHF218318 is:

All the tests performed for O-MAR were successful. Workflow was smooth and no problems occurred.

Additional testing was conducted using phantoms that individually contained three total hip implants with varying materials, one total knee implant and two spine implants (screws and fixation rod, and screws and fixation plate). A comparison between high bandwidth TSE scans, MARS+VAT scans and SEMAC+VAT scans of the phantoms was conducted based on a reduction of artifact size. All testing showed a better artifact reduction using either the MARS+VAT scan or the SEMAC+VAT scan versus the high bandwidth TSE scan. This testing is found in OMAR Test Data DHF218534.

21 CFR 807.92(b)(2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

Validation testing was conducted to show improved visualization of tissue around the orthopedic implant and reduced orthopedic implant artifacts. This was based on the comparison of a high bandwidth TSE scans to MARS+VAT scans and SEMAC+VAT scans. The MARS+VAT or SEMAC+VAT scans should show better tissue visualization and reduced artifacts compared to the high bandwidth TSE scans. This testing was performed on volunteers that had a knee, hip, or lumbar spine implant. Written justification of the use of these implants in testing can be found in the Test Report O-MAR DHF218534 and is based on size and material of construction.

The conclusion from Validation Report DHF217689 is:

The clinical validation of O-MAR has completed successfully. Either the MARS+VAT or SEMAC+VAT scans showed improved tissue visualization and reduced artifacts in comparison to the high bandwidth TSE scan in all test areas.

The conclusion from Exteranl Image Evaluation report DHF229248 is:
A board certified radiologist confirmed that the artifact reduction and more tissue visualization were better with O-MAR (MARS+VAT or SEMAC+VAT) when compared to the FDA cleared sequence (High band width TSE).

No product defects were submitted during validation and no new hazards were identified.

21 CFR 807.92(b)(3): The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section:

The nonclinical and clinical tests have demonstrated that the device is safe and works according to its intended use**.**

O-MAR software does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers O-MAR Software to be substantially equivalent to the above mentioned predicate device.