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PHILIPS

Philips Medical Systems Nederland B.V.

JUN 13 2014

510(k) Summary

MR Elastography

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.
Address:	Veenpluis 4-6 5684 PC Best The Netherlands
Registration No.:	3003768277
Contact Person:	Susan Quick 595 Miner Rd Cleveland, Oh 44143 Fax: (440)-483-4799 E-mail: susan.quick@philips.com
Prepared (date):	2014 March 14
Trade Name of Device:	MR Elastography
Common Name	Software Option for Magnetic Resonance Diagnostic Device
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. Predicate Device: MR-Touch Option
   Manufacturer: GE
   Predicate Device K#: K083421
   Product Code: LNH

2. Predicate Device: syngo MR K13A for the MAGNETOM Systems Aera/Skyra/Avanto/Verio
   Manufacturer: Siemens
   Predicate Device K#: K121434
   Product Code: LNH

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 MR Elastography feature consists of a specialized acquisition; a source of acoustic frequency vibration and means to impart that vibration to the scan subject; an image processing step to produce stiffness maps, confidence maps, and wave images; and an analysis tool to evaluate the parametric images created.

The acquisition is based on the Phase Contrast FFE sequence acquired while imparting a known frequency of vibration into the patient. A set of images with controlled phase differences between the acquisition and the mechanical oscillation is created by synchronizing the mechanical driver with the acquisition at different time delays. The vibration source and connecting equipment are provided by Resoundant Inc. as a complete set. Elasticity images are created from the image data generated by this acquisition strategy using an algorithm developed by Resoundant Inc. and The Mayo Clinic. In addition, wave images and confidence overlays are also produced to provide data quality assurance.

The following elements of MR Elastography are similar to previously cleared devices (refs [2] and [3]):

- The MR Elastography sequence acquires a PC FFE image for each required acoustic phase difference for each slice.
- The scan execution of the MR Elastography acquisition produces a TTL trigger for each TR.
- After reconstruction, the MR Elastography acquisition magnitude and phase images are used in the MR Elastography post-processing package to generate wave images and elasticity images using an algorithm based on those

developed by The Mayo Clinic and Resoundant Incorporated.

- Confidence overlays are generated by the MR Elastography image post-processing package as a guide indicating which voxels may not yield dependable computational results.
- An MR Elastography image analysis tool is available to view images, draw ROI's, and display stiffness information, and provide overlays of the confidence map on the images and overlays of the stiffness map on the anatomical images.

Hardware as part of the MR Elastography feature

The MR Elastography feature includes hardware supplied by Resoundant Incorporated. This hardware consists of an active driver outside of the magnet room and a passive (MR compatible) driver positioned next to the scan subject connected by a length of plastic hose. The vibration from the active driver is transmitted to the passive driver pneumatically through the hose connecting the two drivers. The passive driver is held in place by an elastic belt that is wrapped around the patient. The active driver is a self-contained metal and plastic box that generates the mechanical waves necessary for the MR Elastography examination.

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

MR Elastography is a software and hardware option intended for use on Achieva and Ingenia 1.5T and 3.0T MR Systems for producing images representing tissue stiffness of the abdomen area such as liver and muscle. MR Elastography applies an MR acquisition sequence synchronized with an external source of vibration to produce images representing tissue stiffness (in kiloPascals, kPa). The stiffness image production technique also creates an overlay representing the reliability of the stiffness image production algorithm.

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

MR Elastography contains both hardware and software elements. The hardware elements are supplied by Resoundant, Inc. and consist of an active driver positioned outside the magnet room and a passive driver positioned on the scan subject. The MR Elastography software post-processing package was based on an estimation algorithm provided by The Mayo Clinic and Resoundant, Inc and the final MR Elastography software was developed in conjunction with The Mayo Clinic and Resoundant, Inc. Both the GE MR-Touch (K083421) and the Siemens MR Elastography (K121434) contain the same hardware elements provided by Resoundant, Inc. and both predicates used the same estimation algorithm and worked in conjunction with The Mayo Clinic and Resoundant, Inc. to develop their final software.

MR Elastography acquisitions are substantially equivalent to the existing phase-contrast imaging feature of the previously cleared Achieva and Ingenia1.5T and 3.0T MR systems (K110151). The acquisition, processing and output images are substantially equivalent to the previously cleared predicates, GE MR-Touch (K083421)

and the Siemens MR Elastography (K121434) used in the MAGNETOM Aera and MAGNETOM Skyra. As with the above predicates, the MR Elastography option provides for a sensitive phase-contrast acquisition synchronized with the vibration supplied by the Resoundant hardware. This captures images of the tissue displacements, which are then input to an algorithm to estimate relative stiffness.

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

MR Elastography has been verified to function with the Achieva and Ingenia MR systems. Sample images demonstrate the wave and elastogram outputs. Additionally, included confidence studies prove that MR Elastography produces repeatable results and can reliably differentiate between tissues of different stiffness.

All the tests performed for MR Elastography were successful.

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

The clinical user needs are tested as part of the validation testing.
The clinical validation of MR Elastography is completed successfully. All clinical user needs have passed for Achieva and Ingenia 1.5T and 3T systems.

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 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.

MR Elastography does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers MR Elastography to be substantially equivalent to the above mentioned predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

June 13, 2014

Re: K140666
Trade/Device Name: MR Elastography
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 7, 2014
Received: April 9, 2014

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,

Robert A Ochs

for

Janine M. Morris
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)*
K140666

Device Name
MR Elastography

Indications for Use *(Describe)*
MR Elastography is a software and hardware option intended for use on Achieva and Ingenia 1.5T and 3.0T MR Systems for producing images representing tissue stiffness of the abdomen area such as liver and muscle. MR Elastography applies an MR acquisition sequence synchronized with an external source of vibration to produce images representing tissue stiffness (in kiloPascals, kPa). The stiffness image production technique also creates an overlay representing the reliability of the stiffness image production algorithm.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Robert A Ochs

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:

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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."