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Philips Medical Systems Nederland B.V.

FEB 12 2014

510(k) Summary

mDIXON-Quant

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 Tel: (440)-483-2291 Fax: (440)-483-4799 E-mail: susan.quick@philips.com
Prepared (date):	2013 November 14, Revised 2014 January 24, 2014 February 06
Trade Name of Device:	mDIXON-Quant
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:

Predicate Device:	IDEAL Software Option
Manufacturer:	GE Healthcare
Predicate Device k#:	K103411

Reference Device:	mDIXON
Manufacturer:	Philips Medical Systems Nederland B.V.
Reference Device k#:	K102344

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

mDIXON-Quant acquisition and reconstruction is based on the mDIXON product developed previously. Acquisition relies on a gradient echo acquisition (FFE) including a large number of echoes (6 or more). Furthermore, mDIXON-Quant reconstruction includes the use of multiple spectral peaks of triglyceride fat, correction of the T2* confounding effect and reduction of T1 bias.

mDIXON-Quant allows for water-fat separation and generates Water-only, Fat-only images as well as Out-phase and In-phase images synthesized from the Water and Fat images. Additionally, mDIXON-Quant produces images representing triglyceride fat fraction as well as images representing transverse magnetization relaxation.

The feature requires:
- Specific parameter settings for the mDIXON sequence, within cleared parameter limits, to acquire the MR signals
- A new calculation function to generate the new images for Fat Fraction, T2 *. This function uses a set of MR images as input that is generated in a cleared manner from the acquired MR signals.
- The new images need to be stored and displayed with the appropriate labels for Fat Fraction, T2 *, applying the facilities provided by the cleared platform.

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

mDIXON-Quant:
- is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems
- is a non-invasive triglyceride fat fraction calculation
- is a 3D, single breath-hold acquisition and reconstruction technique
- allows for water-fat separation generating Water-only, Fat-only images as well as Out-phase and In-phase images
- is indicated for magnetic resonance imaging of the liver

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 and measuring ROI)

The technical impact of the feature mDIXON-Quant comprises:
- Methods: modify an existing sequence to acquire the data required for mDIXON-Quant, within the cleared limits provided by the basic MR system.
- Reconstruction: add a new calculation function that generates the new output images (Fat Fraction, T2*-maps and R2* (=1/T2*).
- Patient Administration and Viewing: enable storage and display of the new output images with appropriate labels (SW-M and SW-P).

No off-the-shelf software is used for the feature mDIXON-Quant. The off-the-shelf software used in the basic MR system for the Ingenia and Achieva 1.5T and 3.0T MR systems is cleared by K110151.
The basic MR system provides the features for interoperability and internet connections, which are already cleared. The feature mDIXON-Quant does not have any additions or modifications related to interoperability and connections to an external network.

Hardware platform description
mDIXON-Quant does not require any change of the hardware platform. The main extension introduced by mDIXON-Quant, the new reconstruction algorithm, runs on the Reconstructor computer.

Computer characteristics:
- Manufacturer: HP; Model: Z400 or Z420; Processor speed: ≥3.6 GHz; Memory: 16-32 GB RAM, 1-2 x quad core processors
- Operating system: Windows 7, 64 bits

The mDIXON-Quant algorithm does not add specific requirements to the Ingenia and Achieva 1.5T and 3.0T MR systems as cleared by K110151.

Workflow
For the operator the only new element for the mDIXON-Quant-feature in this clinical routine workflow is:

Protocol selection: The operator selects an ExamCard with mDIXON-Quant protocols

All other steps are not changed. Only in the planscan phase the user may want to change the predefined selection of output image-types. The newly generated image types can be viewed, post-processed, printed and archived as any other image type. The display of the images on the console can be switched between grey-scale and color scale. During post processing the operator can do further analysis (such as calculation of average values in a ROI) using the image processing facilities as provided by the standard platform.

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

All non-clinical testing was performed on a 1.5T Ingenia and a 3.0T Achieva TX.

All Integration testing completed with passing results, with regression testing completing without error messages and greater than 90% of all scans present in the batch running successfully.

All System Verification testing completed with passing results. For the System Verification testing, a dS-Torso, Posterior coil and Anterior coil were used on the Ingenia 1.5T and a Sense-XL-Torso coil was used on the Achieva 3.0T. All Acquisition and Reconstruction, Viewing, Calculation, and Performance testing passed. In the Acquisition and Reconstruction testing, there were no error messages, scan time was < 20 seconds and FF and T2* images were available. In the Viewing testing, all images opened in gray scale and the Look-Up Table showed the images in the expected colors. In the Calculation testing, the ROI could be drawn and two values of area and mean were displayed. For the Performance testing, no error messages were displayed during SW startup, phantom positioning, examcard loading, survey scan activation, and images were generated in < 5 minutes.

For the Quantification Performance testing, test results showed that the FF accuracy is ±3.5% for both field strengths and all possible parameter combinations, and the T2* range and reproducibility is 1.5% for both field strengths.

Overall, all tests performed for mDIXON-Quant were successful. While using mDIXON-Quant the system didn't crash or hang-up. Workflow was smooth and no problems occurred.

All defects have been analyzed and are confirmed that they are not safety defects and will not cause any hazardous situation on using this application.

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

The clinical user needs were tested as part of the validation testing.

The same systems and coils used in the Verification testing were used for the Validation testing. mDIXON-Quant produced Fat Fraction and T2* images, and operator could create a ROI in the acquired images. All protocol steps as stated in the test plan, completed successfully. The mDIXON-Quant protocols were scanned in 13.6sec for 3T and in 14.6sec for 1.5T. All volunteers were able to hold their breath for that time. As such, the clinical validation of mDIXON-Quant 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 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.

The mDIXON-Quant 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 mDIXON-Quant to be substantially equivalent to the above mentioned predicate device.

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

February 12, 2014

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

Re: K133526
Trade/Device Name: mDIXON-Quant
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 14, 2013
Received: November 15, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Michael D. O'Hara 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 on last page.

510(k) Number *(if known)*
K133526

Device Name
mDIXON-Quant

Indications for Use *(Describe)*

mDIXON-Quant:
- is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems
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- is indicated for magnetic resonance imaging of the liver

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)*

Michael D. O'Hara

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.

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