K131241

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Philips Medical Systems Nederland B.V.

510(k) Summary

SWIp

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)-483-4918 E-mail: susan.quick@philips.com
Prepared (date):	2013 April 29
Trade Name of Device:	SWIp
Classification:	Class II
Regulatory Section:	Magnetic Resonance Diagnostic Device. 892.1000
Product Code:	90LNH

AUG 30 2013

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

1. Predicate Device: ACHIEVA R4 1.5T and ACHIEVA R4 3.OT (aka Ingenia)
   Manufacturer: Philips Healthcare
   Predicate Device k#: K110151

2. Predicate Device: Discovery MR450
   Manufacturer: GE Healthcare
   Predicate Device k#: K083147

3. Predicate Device: MAGNETOM Trio a Tim System
   Manufacturer: Siemens Medical Solutions
   Predicate Device k#: K050200

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

SWIp (Susceptibility Weighted Imaging with Phase enhancement) exploits the susceptibility differences between tissues. It is based on a 3D FFE acquisition, multi-echo compatible, generating high resolution magnitude and phase images.

Phase images are unwrapped to create Susceptibility Weighted Phase (SW-P) images highlighting phase changes due to local susceptibility differences. The magnitude images and SW-P information are combined to generate Susceptibility Weighted Magnitude (SW-M) images with enhanced susceptibility contrast. SW-M images show de-oxygenated blood, such as veins, as hypo-intense signals.

The feature requires:

- Specific parameter settings for the 3D FFE sequence, within cleared parameter limits, to acquire the MR signals
- A new calculation function to generate SW-M and SW-P images. 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 (SW-M and SW-P), applying the facilities provided by the cleared platform.

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

SWIp is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems. It's indicated for magnetic resonance imaging of the Brain. SWIp is a technique using phase information to enhance contrast between tissues presenting susceptibility differences, such as deoxygenated blood or some mineral deposits (e.g. calcium deposits). Due to this contrast enhancement, SWIp images are sensitive for structures containing venous blood such as cerebral venous vasculature. When used in

combination with other clinical information, SWIp may help the expert radiologist in the diagnosis of various neurological pathologies.

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 SWIp comprises:

- Methods: modify an existing sequence to acquire the data required for SWIp, within the cleared limits provided by the basic MR system.
- Reconstruction: add a new calculation function that generates the new output images SW-M and SW-P.
- 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 SWIp. The off-the-shelf software used in the basic MR system for the Ingenia and Achieva 1.5T and 3.0T MR systems machine is cleared by K110151.

SWIp is not designed to be connected to an external network.

Hardware platform description

SWIp does not require any change of the hardware platform. The main extension introduced by SWIp, the new reconstruction algorithm, runs on the Reconstructor computer.

Computer characteristics:

- Manufacturer: HP; Model: Z400 or Z420; Processor clock: 3.6 GHz; RAM: 16-32 GB RAM; Processors: 1-2 x quad core
- Operating system: Windows 7, 64 bits

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

Workflow

The only new element for the operator of the SWIp-feature in this clinical routine workflow is:

1. Protocol selection: The operator selects an ExamCard with SWIp protocols
2. Planscan phase: Optionally the operator may want to change the predefined selection of output image-types

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:

The non-clinical tests that are included in the submission are as follows

- DHF176222 Verification Test Report

The conclusion from testing the device is:
All the tests performed for SWIp were successful. While using SWIp, the system didn't crash or hang-up. Workflow was smooth and no problems occurred.

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.

- DHF176223 Validation Test Report

The conclusion from testing the device is:
The clinical validation of SWIp has completed successfully. All clinical user needs are 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 SWip 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 SWIp 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

August 30, 2013

Re: K131241
Trade/Device Name: SWIp
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: July 30, 2013
Received: July 31, 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

Indication for use

510(k) Number (if known): K131241

Device Name: **SWIp Software option for ACHIEVA 1.5T and 3.0T, INGENIA 1.5T and 3.0T MR Systems**

Indication For Use:

SWIp is a software option intended for use on Achieva and Ingenia 1.5T & 3.0T MR Systems. It's indicated for magnetic resonance imaging of the Brain. SWIp is a technique using phase information to enhance contrast between tissues presenting susceptibility differences, such as deoxygenated blood or some mineral deposits (e.g. calcium deposits). Due to this contrast enhancement, SWIp images are sensitive for structures containing venous blood such as cerebral venous vasculature. When used in combination with other clinical information, SWIp may help the expert radiologist in the diagnosis of various neurological pathologies.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) K131241