K102344

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV - 9 2010

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

General information

Company Name:	Philips Medical Systems Nederland BV
Address:	Veenpluis 4-6 5684 PC Best, Netherlands,
Registration No.:	3003768277
Contact person:	Lynn Harmer Sr. Manager, Regulatory Affairs Tel: (425) 487-7312 Fax: (425) 487-8666 Lynn.Harmer@Philips.com
Date Prepared:	**August 16, 2010**
Device (Trade) Name:	**mDIXON Software option for INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T MR systems**
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Regulatory Number:	892.1000
Classification:	Class II
Product code:	90L--NH 90L--NI
Performance standards:	NEMA voluntary standards, FDA MR Diagnostic Device Guidance, UL and IEC 60601 appropriate safety standards and/or draft standards are used.

Predicate Device(s):
INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T MR systems Release 2.5-series (FDA reference K063559) and the IDEAL software option (FDA reference K072998) are predicate devices for mDIXON software option.

Intended Use:
mDIXON is a software option intended for use on Intera 1.5T, Achieva 1.5T and Achieva 3T. MR Systems. It is indicated for magnetic resonance imaging of the chest, abdomen and pelvis. mDIXON is a multipoint (echo) method for 3D clinical imaging with the possibility to reformat into multiple planes (axial, sagittal and coronal). mDIXON provides improved fat suppression, increased scan speed in addition and/or an improved signal-to-noise relative to other current 3D volumetric fat suppressed imaging methods

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Device description:
The modified-DIXON (mDIXON) sequence is a novel two and multi-point method for 2D and 3D water-fat magnetic resonance imaging. mDIXON is a modification of previous DIXON implementations due to the unrestricted echo-time (TE) approach. This allows more freedom in protocol optimization resulting in more efficient (faster) scanning and an increase in signal to noise (SNR). Additionally, it provides a technique for improved fat suppression (in comparison to other current 3D volumetric fat suppressed imaging methods.) While the primary use is for torso imaging, it may also be applicable to other anatomies requiring in- and opposed-phase, water-only, and/or fat-only imaging. While the current 3D volumetric fat suppressed technique (e-THRIVE) is an imaging method, mDIXON is a multi echo sequence with multiple gradient echo read-outs. Phase and amplitude of complex data acquired at different echo times are used to separate the water and fat signals. The separation is made possible by the chemical shift difference between water and fat. The resultant images can be reconstructed to produce "water-only" images, "fat-only" images and in-phase/opposed-phase images (synthesized from the acquired multiecho images). The fat suppression is enhanced especially at the edges of larger fields of view due to the mDIXON reconstruction algorithm and its use of the chemical shift difference between water and fat.

1 Summary of non-clinical testing

The INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T systems comply with the international IEC and ISO standards identified in the submission. Modifications to the requirements of the predicate device were developed under an approved design control process in conformance to the standard EN ISO 13485:2003.

mDIXON verification and validation tests were performed on the complete system relative to the requirement specification and risk management results. Corresponding test results are included in this submission.

Based on the test results Philips Medical Systems believes that the INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T systems are still as safe and effective with additional mDIXON software option.

2 General Safety and Effectiveness

mDIXON software option does not induce any other risks than already indicated for their predicate devices with the same safety and effectiveness.

3 Substantial Equivalence

It is the opinion of Philips Medical Systems that the Philips mDIXON Software option for INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T MR systems is substantially equivalent to the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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Re: K102344
Trade/Device Name: mDixon Software option for INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 17, 2010
Received: August 18, 2010

Dear Ms. Harmer:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Appendix A2

Indication for use

NOV - 9 2010

510(k) Number (if known): _____

Device Name : **mDIXON Software option for INTERA 1.5T, ACHIEVA 1.5T and ACHIEVA 3.0T MR systems**

Indication For Use :

mDIXON is a software option intended for use on Intera 1.5T, Achieva 1.5T and Achieva 3T MR Systems. It's indicated for magnetic resonance imaging of the chest, abdomen and pelvis.

mDIXON is a multipoint(echo) method for 3D clinical imaging with the possibility to reformat into multiple planes (axial, sagittal and coronal). mDixon provides improved fat suppression, increased scan speed in addition and/or an improved signal-to-noise.

Prescription Use ___X____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of In vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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