K01 3858

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

JAN 2 2 2002

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) System
Proprietary Name:	Infinion 0.6T MR Imaging System
Establishment Registration:	*Manufacturer:* Philips Medical Systems MR Technologies Finland, Inc. P.O. Box 185 FIN-00511 Vantaa, Finland Phone: +358-9-2535-9300 Fax: +358-9-2535-9600 FDA Facility Registraton #9680194 *United States Representative:* Philips Medical Systems (Cleveland), Inc. 595 Miner Road Highland Heights, Ohio 44143 Contact: Duane C. Praschan Phone: (440) 483-3000 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Infinion 0.6T MR Imaging System does not change the existing indications as defined below.

The Infinion 0.6T MR Imaging System is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

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3. Device Description

This submission describes the hardware and software changes for the Philips' 0.6T Open Magnetic Resonance Imaging system, the Infinion 0.6T.The package also includes additional imagin sequences and acquisition/construction techniques. However, the basic features are unchanged.

4. Safety and Effectiveness

The functionality included in Philips' Infinion 0.6T MR Imaging System is similar in technological characteristics and intended use to the Proview 0.23T MR. The following table has been created to demonstrate their substantial equivalence.

Substantial Equivalence Chart

Parameter	Infinion 0.6T MR Imaging System	Predicate Device – Philips Proview 0.23T System (K974844)
Computer Subsystem		
Display/database system:	Same.	Single display for system operation and image reviewing, workstation tower, moveable keyboard and mouse, CD-ROM. Allows for simultaneous scanning and image reconstruction/manipulation. Image storage via magneo-optical disk.
Network communications:	DICOM Query/Retrieve, DICOM Modality WL Management.	Display/Database computer and scan reconstruction hardware connected together by fast Ethernet communications system. DICOM compliant for transfer of images to other systems.
Gradient Subsystem		
Gradient Coils:	Same.	Water-cooled self-shielded gradient system.
Max. Gradient Strength:	20 mT/m	16 mT/m (XY), 18 mT/m (Z)
Max. Slew Rate:	40 T/m/s	25 mT/m/msec (XY), 40 mT/m/msec (Z).
RF Subsystem		
RF Amplifiers:	Max power 9 kW.	5 kW solid state.
RF transmitter coils:	Same but with tuning adjusted to proton resonance at 0.6T field strength instead of 0.23 T, and with water cooling.	Upper and lower, planar coils, integrated in the magnet.

Parameter	Infinion 0.6T MR Imaging System	Predicate Device – Philips Proview 0.23T System (K974844)
Receive only RF coils:	Head (phased array two-channel) Head and Neck (phased array four-channel). Neck (phased array two-channel) Extremity (phased array two-channel) Body & Spine, different sizes (phased array two-channel) Multipurpose, different sizes (linear single-channel)	Head (phased array two-channel). Brain (phased array two-channel). Head and Neck (phased array four-channel, formerly Vascular Head and Neck). Neck (phased array two-channel). Extremity (phased array two-channel). Body and Spine, different sizes (phased array two-channel) Flexible Spine (phased array two-channel). Flexible Multipurpose, different sizes (linear single-channel). Small Extremity (phased array two-channel, earlier name Small Joints). Large Neck (phased array two-channel).
Receive only coil connection:	All receive only coils plug into the RF connectors in both ends of the patient couch.	All receive only coils plug into the RF connector on the front of the magnet façade.
Magnet Subsystem		
Magnet Type:	0.6 T superconducting	0.23 T iron-core electromagnetic.
Patient Handling		
Patient couch:	Motorized movement in three orthogonal dimensions. Optional trolley which can be used for transporting the couch upper part together with the coil and patient. Couch weight capacity is 220 kg. Remote control of the couch in horizontal direction.	Computer and couch controlled patient transport system with 200 kg weight capacity. Optional couch with vertical movement.
Patient positioning:	Same laser positioning marker. Additional automated stepping capabilities.	Laser positioning marker for accurate placement of patient at isocenter.
Patient communication:	Same.	Two-way intercom system and hand-held audio alarm.
Magnet Enclosure		
Magnet Façade:	Same.	Fiberglass enclosure.
Controls:	LCD display above bore capable of displaying system status. Two keypads on either side of bore for system controls.	LED display capable of display system status. Control panel in upper front pole.
Power Distribution Subsystem		
Subsystem components:	Same.	Isolation transformer, transient suppression circuitry, and power distribution center all contained in a single cabinet.
Operating Software		
Base Software: MRGP software:	Same. Same.	Windows 2000 based Graphical User Interface and scan / reconstruction software with multi-tasking capability. Interventional MRI capabilities.

Parameter	Infinion 0.6T MR Imaging System	Predicate Device – Philips Proview 0.23T System (K974844)
Imaging sequences		
Main features include:	Field Echo, Spin Echo, Dual Echo, Dual Spin Echo, Inversion Recovery, Dual Inversion Recovery, Fast Spin Echo, EXPRESS, CBASS, MRCP, MRA, STIR, FLAIR,TSHIRT, RF-FAST, CE-FAST, DWISE.	Field Echo, Spin Echo, Dual Echo, Inversion Recovery, Fast Spin Echo, CBASS, MRCP, MRA, STIR.
Acquisition and reconstruction techniques		
Main features include:	Same and additionally MAO, MAST, presaturation, chemical fat saturation, phase conjugate symmetry, read conjugate symmetry, true res, true slice, elliptic encoding, RAM, CODA, MTC, dynamic examination curve, contrast dynamic imaging, reconstruction filters, respiratory gating, multiplanar reconstruction, maximum intensity projection, phase correction, fat/water suppression, ADC map.	Presaturation, MAST, ODA, PCS, no phase wrap-around, no slice wrap around, dynamic imaging, cardiac gating, optimized bandwidth, turbo multislice.
Time Varying Magnetic Field		
Normal Operating Mode:	According to 60601-2-33 FDISscript 2001-11-02.	dB/dt ≤ 20 T/s
First Level Controlled Operating Mode:	According to 60601-2-33 FDISscript 2001-11-02.	Not applicable.
Radiofrequency Absorption		
Normal Operating Mode:	Same.	Limited to a maximum level of 1.2 W/kg.
First Level Controlled Operating Mode:	Same.	Limited to a maximum value of 3.2 W/kg.
Acoustic Noise		
Typical:	87 dBA (average) 102 dB (peak)	<85 dBA (average, normal clinical sequences)
Worst Case:	91 dBA (average) 104 dB (peak)	84 dBA (average) 98 (peak)
Intended Use and Indications for Use		
	Same.	The Proview System is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2002

Mr. Duane Praschan
Manager, Regulatory Affairs
Philips Medical Systems
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K013858
Trade/Device Name: Infinion 0.6T MR Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: November 16, 2001
Received: November 21, 2001

Dear Mr. Praschan:

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 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); 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.

This letter will allow you to begin marketing your device as described in your 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013858

Device Name: Infinion 0.6T MR Imaging System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013858