K024042

FEB 0 4 2003

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) System
Proprietary Name:	Panorama Enhancements
Establishment Registration:	**Manufacturing Location:** Philips Medical Systems MR Technologies Finland Oy P.O. Box 185 Vantaa, Finland FIN-00511 Phone: 358925359300 FDA Facility Registration: #9680194 FDA Owner #1580240 **Contact:** Attn: Duane C. Praschan Philips Medical Systems (Cleveland) 595 Miner Road Highland Heights, OH 44143 Phone: 440-483-5743
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Panorama Enhancements do not change the existing indications for the Panorama 0.6T or 0.23T MR imaging systems as defined below:

The Panorama 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 training physician, these images yield information that can be useful in the determination of a diagnosis.

3. Device Description

Philips' Panorama Enhancements includes changes to the operating limits for dB/dt and additional software improvements.

Safety and Effectiveness

The functionality included in the Panorama Enhancements are similar in technology characteristics and intended use to the Panorama 0.6T and 0.23T MR Imaging Systems and Philips' Intera family.

Substantial Equivalence Chart

Parameter	**Panorama 0.6T MR Imaging System**	**Predicate Device - Philips Panorama 0.6T System K013858 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796**	**Panorama 0.23 T MR Imaging System**	**Predicate Device - Philips Panorama 0.6T System K013858 - Philips Panorama 0.23 T System K974844 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796**
Gradient Subsystem				
Gradient Coils:	Same.	Water-cooled self-shielded gradient system. **K013858**	Same.	Water-cooled self-shielded gradient system. **K974844**
Max. Gradient Strength:	23 mT/m.	20 mT/m **K013858**	21 mT/m	16 mT/m (x,y direction), 18 mT/m (z direction) **K974844**
Max. Slew Rate:	75 T/m/s.	40 T/m/s **K013858**	50 T/m/s	25 T/m/s (x,y direction), 40 T/m/s (z direction) **K974844**
RF Subsystem				
RF amplifiers:	Same.	Max power 9 kW **K013858**	Same.	5 kW solid state **K013858**
RF transmitter coils:	Same.	Upper and lower, planar coils, integrated in the magnet, water cooling. Tuning adjusted to 0.6T field strength. **K013858**	Same.	Upper and lower, planar coils, integrated in the magnet. Tuning adjusted to 0.23T field strength. **K013858**
Receive only RF coils:	Same and Synergy Head and Neck	Head, Head and Neck, Neck, Extremity, Body and Spine, Multipurpose (different sizes), TMJ, Breast, Shoulder. **K013858**	Same and Synergy Body.	Head, Brain, Head and Neck, Neck, Extremity, Body and Spine (different sizes), Flexible spine, Flexible Multi-Purpose (different sizes), Small Extremity **(K974844)** Breast **(K002539,** MRI Devices Corp.) Large Neck **(K981959 Picker International, Inc.)** TMJ **(013528, USA Instruments, Inc.)** Shoulder **(K983143,USA Instruments, Inc.)**
Magnet Enclosure				

Parameter	Panorama 0.6T MR Imaging System	**Predicate Device - Philips Panorama 0.6T System K013858 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796**	Panorama 0.23 T MR Imaging System	**Predicate Device - Philips Panorama 0.6T System K013858 - Philips Panorama 0.23 T System K974844 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796**
Magnet Façade:	New design, cover backdoor of ABS, otherwise material the same.	Fiberglass enclosure. **K013858**	New design, cover backdoor of ABS, otherwise material the same.	Fiberglass enclosure. **K974844**
Operating Software				
Base Software:	Same.	Windows 2000 based Graphical User Interface and scan / reconstruction software with multi-tasking capability. **K013858**	Same.	Windows 2000 based Graphical User Interface and scan / reconstruction software with multi-tasking capability. **K013858**
MRGP software:	Same.	Interventional MRI capabilities. **K013858**	Same.	Interventional MRI capabilities. **K013858**
Imaging sequences				
Main features include:	Same.	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. **K013858**	Same.	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. **K013858**
Acquisition and reconstruction techniques				

Parameter	Panorama 0.6T MR Imaging System	Predicate Device - Philips Panorama 0.6T System K013858 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796	Panorama 0.23 T MR Imaging System	Predicate Device - Philips Panorama 0.6T System K013858 - Philips Panorama 0.23 T System K974844 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796
Main features include:	Same. Same.	Presaturation, MAST, ODA, PCS, no phase wrap-around, no slice wrap around, dynamic imaging, cardiac gating, optimized bandwidth, turbo multislice. 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. **K013858** SENSE capability. **K001796 SyncraScan**	Same.	Presaturation, MAST, ODA, PCS, no phase wrap-around, no slice wrap around, dynamic imaging, cardiac gating, optimized bandwidth, turbo multislice. 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. **K013858** SENSE capability. **K001796 SyncraScan**
User Interface				
	Layout change, see Figure 2b.	Layout, see Figure 2a.	Layout change, see Figure 2b.	Layout, see Figure 2a.
Time Varying Magnetic Field				

Parameter	Panorama 0.6T MR Imaging System	Predicate Device - Philips Panorama 0.6T System K013858 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796	Panorama 0.23 T MR Imaging System	Predicate Device - Philips Panorama 0.6T System K013858 - Philips Panorama 0.23 T System K974844 - Philips Intera family (0.5T, 1.0T, 1.5T) K001796
Normal Operating Mode:	≤ 35.4 T/s (IEC60601-2-33, second edition, directly determined)	According to IEC 60601-2-33 FDIS script 2001-11-02, default. **K013858**	≤ 35.4 T/s (IEC60601-2-33, second edition, directly determined)	≤ 40 T/s **K974844**
First Level Controlled Operating Mode:	≤ 44.3 T/s (IEC60601-2-33, second edition, directly determined)	According to IEC 60601-2-33 FDIS script 2001-11-02, default. **K013858**	≤ 44.3 T/s (IEC60601-2-33, second edition, directly determined)	≤ 60 T/s **K974844**
Radiofrequency Absorption				
Normal Operating Mode:	Same.	Limited to a maximum level of 1.2 W/kg. **K013858**	Same.	Limited to a maximum level of 1.2 W/kg. **K974844**
First Level Controlled Operating Mode:	Same.	Limited to a maximum value of 3.2 W/kg. **K013858**	Same.	Limited to a maximum value of 3.2 W/kg. **K974844**
Acoustic Noise				
Typical:	Same.	87 dBA (average) 102 dBA (peak) **K013858**	Same.	A-weighted average value < 85 dBA **K974844**
Worst Case:	Same.	91 dBA (average), 104 dB (peak) **K013858**	Same.	A-weighted average value < 85 dBA, 98 dB peak **K974844**

Parameter	Panorama 0.6T MR Imaging System	**Predicate Device** **- Philips Panorama 0.6T System K013858** **- Philips Intera family (0.5T, 1.0T, 1.5T) K001796**	Panorama 0.23 T MR Imaging System	**Predicate Device** **- Philips Panorama 0.6T System K013858** **- Philips Panorama 0.23 T System K974844** **- Philips Intera family (0.5T, 1.0T, 1.5T) K001796**
Intended Use and Indications for Use				
	Same, note the system name change.	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. **K013858**	Same, note the system name change.	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. **K013858**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2003

Mr. Duane C. Preschan
Manager, MR Regulatory Affairs
Philips, Medical Systems, Inc.
595 Miner Road
HIGHLAND HEIGHTS OH 44143

Re: K024042
Trade/Device Name: Panorama Enhancements
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: November 22, 2002
Received: December 6, 2002

Dear Mr. Preschan:

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 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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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): K024042

Device Name: Panorama Enhancements

Indications for Use:

Intended Use

The Panorama Enhancements do not change the existing indications as defined below.

The Panorama 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024042

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