K02 4066

SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

FEB 0 4 2003

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) System
Proprietary Name:	Infinion Software Features
Establishment Registration:	Philips Medical Systems 595 Miner Road Highland Heights, Ohio 44143 Contact: Duane Praschan Phone: (440) 483-5743 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 Software Features do not change the existing indications for the Infinion 1.5T MR Imaging Systems as defined below.

The Infinion 1.5T 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.

Diffusion tensor imaging is indicated for use by producing magnetic resonance (MR) images whose contrast is dependent on the local diffusion coefficient of water. Diffusion tensor imaging can be used to image the directional dependence of the diffusion coefficient in tissue with restricted diffusion from tissues with normal diffusion.

3. Device Description

Philips's Infinion Software Features include rapid imaging SENSE, coil uniformity

improvements of CLEAR, rapid imaging using the b-FFE technique, acoustic noise reduction of SofTone and other improvements to current imaging techniques.

4. Safety and Effectiveness

The functionality included in Philips' Infinion Software Features is similar in technology characteristics and intended used to the Philips (formerly Marconi's) Infinion 1.5T MR Imaging System, the Philips Intera (R7.5) Software Package, and the Diffusion Tensor offered by General Electric in K003573.

Substantial Equivalence Chart

Parameter	**Infinion Software Features**	**Predicate Device – Infinion 1.5T Imaging System (K003853), Philips Intera (R7.5) Option (K001796) and General Electric (K003573)**
TIME VARYING MAGNETIC FIELD		
Method	Same	Based on IEC 601-2-33, 2nd ed. (K003853)
Normal Operating Mode	Same	R(t)≤ 0.8 (K003853)
First Controlled Operating Mode	Same	0.8>R(t)≤1.0 (K003853)
Gradient Performance Levels	Same	All
Indications for Use for System	Same	The Infinion 1.5T 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.
SENSE		
Purpose	Same	To reduce scan time by speedup factors applied in any PE direction (K001796)
Operator Choices	Same	- Acceleration factor greater than 1.0 in primary phase encode direction - Acceleration factor greater than 1.0 in secondary phase encode direction (K001796)
CLEAR		
Purpose	Same	B1 receive field uniformity correction (K001796)
Operator Choices	Same	Enable correction for an acquisition (K001796)

Parameter	Infinion Software Features	Predicate Device – Infinion 1.5T Imaging System (K003853), Philips Intera (R7.5) Option (K001796) and General Electric (K003573)
Diffusion Tensor		
Purpose	Same	Designed to create images that differentiate tissues with restricted diffusion from tissues with normal diffusion and image the directional dependence of the diffusion coefficient in tissue such as white matter. (K003573)
Method	Same	SS-DW-EPI(K003573)
Indications for use	Same	Diffusion tensor imaging produced magnetic resonance (MR) images whose contrast is dependent on the local diffusion coefficient of water. Diffusion tensor imaging can be used to image the directional dependence of the diffusion coefficient in tissue with restricted diffusion from tissues with normal diffusion. (K003573)
SofTone		
Purpose	Same	Reduce acoustic noise (K001796)
Method	Same	Reduce slew rates (K001796)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2003

Mr. Duane Praschan
Manager, MR Regulatory Affairs
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

Re: K024066
Trade/Device Name: Infinion Software Features
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: December 6, 2002
Received: December 9, 2002

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 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): K02 40 66

Device Name: Infinion Software Features

Indications for Use:

Intended Use

The Infinion Software Features does not change the existing indications as defined below.

The Infinion 1.5T 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.

Indications for Use

Diffusion tensor imaging produced magnetic resonance (MR) images whose contrast is dependent on the local diffusion coefficient of water. Diffusion tensor imaging can be used to image the directional dependence of the diffusion coefficient in tissue with restricted diffusion from tissues with normal diffusion.

(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 K024066

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

(Optional Format 1-2-96)