K041602

JUL 2 6 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 Best, Netherlands, 5684 PC
Registration No.	:	1217116
Contact person	:	Joseph S. Arnaudo. Sr., Regulatory Manager Tel: (425) 482-8958 Fax: (425) 487-8666 Joseph S. Arnaudo@Philips.com

Device (Trade) Name	:	**PANORAMA 1.0T.**
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH
Performance standards	:	NEMA voluntary standards, FDA MR Diagnostic Device Guidance, UL and IEC 601 appropriate safety standards and/or draft standards are used

Predicate Device(s):

The **PANORAMA 1.0T** is a magnetic resonance diagnostic device with a vertical field based on the same platform as its predicate device cylindrical **INTERA ACHIEVA** (ref. K031815).

Indications for use:

PANORAMA 1.0T is a Magnetic Resonance Diagnostic Device intended for general diagnostic use that produces transverse, sagittal, coronal and oblique cross-sectional images based upon ^{1}H metabolites, and that displays the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

Device description:

The **PANORAMA 1.0T** provides the same functionalities as its predicate device. It is a magnetic resonance diagnostic device with a vertical field. It uses a super conducting actively shielded magnet with a static field of 1.0 Tesla and a dockable wheeled patient table (couch).

General Safety and Effectiveness.

The **PANORAMA 1.0T** does not induce any other risks than already indicated for the predicate devices. It has the same safety and effectiveness as its predicate device.

Substantial Equivalence.

It is the opinion of Philips Medical Systems that the **PANORAMA 1.0T** is substantially equivalent to its predicate device.

End

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2004

Mr. Joseph S. Arnaudo
Senior Regulatory Manager
Philips Medical Systems North America
22100 Bothell Everett Highway
BOTHELL WA 98021

Re: K041602
Trade/Device Name: PANORAMA 1.0T
Regulatory Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: June 9, 2004
Received: June 14, 2004

Dear Mr. Arnaudo:

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 such 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): K041602

Device Name : **PANORAMA 1.0T.**

Indication For Use :

PANORAMA 1.0T is a Magnetic Resonance Diagnostic Device intended for general diagnostic use that produces transverse, sagittal, coronal and oblique cross-sectional images based upon ^{1}H metabolites, and that displays the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

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 Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041602

(Optional Format 1-2-96)