K033662

FEB - 2 2004

510(k) Summary

(As required by 21CFR 807.92)

I General Information

Classification: Class II
Classification Number 90 MOS
Magnetic Resonance Imaging (MRI) Accessory

Common/usual name: Magnetic Resonance Imaging (MRI) Coil

Proprietary Name: Synergy Spine Array coil (SSA)

Predicate device(s): Integrated Spine Array (ISA) coil for Philips Infinion 1.5T system

Establishment Registration:

Manufacturer:
Philips Medical Systems MR Technologies Finland, Inc.
Äyritie 4
FI-01510 Vantaa, Finland
Phone: +358 9 2535 9300
Fax: +358 9 2535 9600
FDA Facility Registration #9680194
FDA Owner #1217116

United States Contact:
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
Highland Heights, Ohio 44143
Contact: Duane C. Praschan
Phone: (440) 483-3000
FDA Registration #1525965

Performance Standards: No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

II Safety and Effectiveness Information Supporting Substantial Equivalence

- **Intended use**
  The intended use of the Panorama 0.6T SSA coil is to be used in MR imaging of the spine. The Panorama 0.6T system is a whole body scanner and 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 internal structure of the head, extremities and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination

of a diagnosis.

The SSA coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Regions: Thoracic and Lumbar or spine and sternum

Nuclei Excited: Hydrogen

Device Description
The SSA coil is an optional accessory to the Panorama 0.6T MR system. This receive-only coil is designed for use when large imaging volume is required or when the patient is large or when easy usage is essential.

- **Relevant Technological Characteristics**
  The technological characteristics of the SSA coil are similar to the predicate ISA coil. The potential benefits associated with the SSA coil include improved patient handling and possibilities to image larger patients than with the Body & Spine coils in the Panorama 0.6T system.

  Safety & Effectivness
  The SSA coil is substantially equivalent to the Philips ISA Coil in safety and effectiveness. The safety parameters (Static Field, dB/dt, SAR and Acoustic Noise) and the performance parameters (SNR, Image Uniformity, Geometric Distortion, Slice Thickness & Spacing, and Spatial Resolution) for the Panorama 0.6T MR system are unaffected with the SSA coil.

- **Substantial Equivalence**
  Phantom and clinical studies were performed to support the claim of substantial equivalence and to show that the technological differences do not raise new questions pertaining to safety and effectiveness.

- **Conclusion**
  It is the opinion of Philips Medical Systems that the SSA coil of the Panorama 0.6T system is substantially equivalent to the predicate ISA coil of the Philips Infinion 1.5T system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2004

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

Re: K033662
Trade/Device Name: Synergy Spine Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: November 18, 2003
Received: November 21, 2003

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 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): K033662

Device Name: **SYNERGY SPINE ARRAY COIL**

Indications for Use:

Intended Use

The Synergy Spine Array Coil does not change the existing indications as defined below.

The Panorama 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.

Indications for Use

The Synergy Spine Array Coil is indicated for use in the following anatomic regions and with designated nuclei:

Anatomic Regions:	Thoracic and lumbar
Nuclei Excited:	Hydrogen

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

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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033662