K01 2200

AUG - 3 2001

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Medical Systems
PO Box 414
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Contact Person: Larry A. Kroger Ph.D.
Manager, Regulatory Programs

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Date Prepared: July 12, 2001

Device Name:

GE Signa 1.5T TwinSpeed Magnetic Resonance System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The Signa 1.5T TwinSpeed System is substantially equivalent to the currently marketed Signa CVMR Magnetic Resonance System (K980114) and the Signa Horizon Cx (K962061).

Device Description:

The Signa 1.5T TwinSpeed incorporates the Signa Horizon Cx (K962061) and the Signa CVMR Magnetic Resonance System (K980114) gradient performance into a single MR device with a 60 cm patient aperture. Previously cleared software options, coils, and other accessories may be used with the Signa 1.5T TwinSpeed.

Indications for Use:

The Signa 1.5T TwinSpeed Magnetic Resonance System is a whole body scanner designed for shorter scan times. The Signa TwinSpeed is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by the Signa TwinSpeed system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Comparison with Predicate Device:

The Signa TwinSpeed is a modification of the Signa CVMR MR system (K980114) by combining the gradient performance of the CVMR and Signa Horizon Cx (K962061) into a single MR device. It has

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the same basic technological characteristics, and, uses the same basic design, construction, and materials. It has the same intended use, and operating modes as the predicate device.

Summary of Studies:

Testing was performed to demonstrate that the design modifications to the Signa 1.5T TwinSpeed meet predetermined acceptance criteria.

Conclusion:

The results of the testing described above demonstrate that the Signa 1.5T TwinSpeed is substantially equivalent to the currently cleared Signa CVMR and Signa Horizon Cx magnetic resonance systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Larry Kroger, Ph.D.
Regulatory Programs Manager
GE Medical Systems
General Electric Company
P.O. Box 414
MILWAUKEE WI 53201

Re: K012200
GE Signa 1.5T Twinspeed Magnetic Resonance System
Dated: July 12, 2001
Received: July 13, 2001
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 (s)

510(k) Number (if known): K012200

Device Name: Signa 1.5T TwinSpeed

Indications For Use:

The Signa 1.5T TwinSpeed Magnetic Resonance System is a whole body scanner designed for shorter scan times. The Signa TwinSpeed is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by the Signa TwinSpeed system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012200