



SEP 8 1999

K 99 2135

GE Medical Systems

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P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter

Larry A. Kroger, Ph.D., 414-544-3894, June 18, 1999

- Identification of the Product

Signa Profile/i Magnetic Resonance System

Manufacturer Address:

GE Yokogawa Medical Systems, Ltd.
4-7-127, Asahigaoka, Hino-Shi
Tokyo, 191 Japan

- Marketed Devices

The Signa Profile/ System is substantially equivalent to the currently marketed Signa Profile System. The Signa Profile/i Magnetic Resonance System adds interventional applications capability and a new Gradient Coil with a slew rate of 25 mT/m/sec.

- Device Description

The Signa Profile/i System is a modification to the Signa Profile/i MR Systems which utilizes a permanent magnet to acquire 2D single-slice and multi-slice, and 3D volume images. In addition to the wide variety of pulse sequences provided to the Signa Profile operator, such as inversion recovery, spin echo, gradient echo, gradient recalled, and steady state, and free precession acquisitions, the Signa Profile/i operator has the ability for shorter scan times due to expanded gradient capabilities. Imaging options such as cardiac gating, peripheral gating, flow compensation and fat/water suppression are provided to suppress artifacts due to physiological motion and improve image quality.

- Indications for Use

The Signa Profile/i system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Profile/i system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculoskeletal, vascular, cardiac, and neuro systems. The images produced by the Signa Profile/i 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.



SUMMARY OF SAFETY AND EFFECTIVENESS

Due to the 'open' design of the system, the Profile/i can also be utilized for imaging during interventional procedures when performed with MR compatible devices such as, in-room display, nad MR safe biopsy needles.

- **Comparison with Predicate**

The Signa Profile/i System is comparable to the Signa Profile Systems with the main difference being with the Gradient coil which allows for expanded gradient capabilities, enabling shorter scan times.

- **Summary of Studies**

The Signa Profile/i System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard and IEC 601-2-33 Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. The Signa Profile/i System is comparable to the Signa Profile MR Systems.

- **Conclusions**

It is the opinion of GE that the Signa Profile/i System is substantially equivalent to the Signa Profile MR Systems. The Signa Profile/i Magnetic Resonance System does not include any new indications for use, nor does use of this device result in any new potential hazards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
General Electric Medical Systems
P.O. Box 414, W-709
Milwaukee, Wisconsin 53201

Re: K992135
Signa Profile/I Magnetic Resonance System
Dated: June 18, 1999
Received: June 24, 1999
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 (Pre-market 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) 594-4613. 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" (21 CFR 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992135

Device Name: Signa Profile/i Magnetic Resonance System

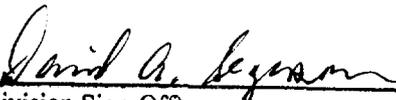
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Due to the 'open' design of the system, the Profile/i may also be utilized for imaging during interventional procedures when performed with MR compatible devices such as, in-room display and MR safe biopsy needles.

(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, ENT,
and Radiological Devices

510(k) Number K992135

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____