

K992746

NOV - 9 1999

**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, August 13, 1999

- Identification of the Product

Signa HFO/i Magnetic Resonance System

Manufactured by: GE Medical Systems  
3200 N. Grandview Blvd.  
Waukesha, WI 53188

- Marketed Devices

The Signa HFO/i Magnetic Resonance System is substantially equivalent to the currently marketed Signa Horizon Magnetic Resonance System with the main difference being a 0.7T Open Magnet while the Signa Horizon System has the typical 1.0T cylindrical magnet. The magnet looks like the Signa Profile 0.2T permanent magnet.

- Device Description

The Signa HFO/i Magnetic Resonance System is a modification to the Signa Horizon CX Magnetic Resonance System which utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. The Signa HFO/i MR System is an open style magnet operating at 0.7T. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences. Images are acquired and reconstructed using 2D and 3D Fourier transformation techniques. The system is intended for high resolution anatomical applications and shorter scan times than the Signa Profile System.

- Indications for Use

The Signa HFO/i system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The HFO/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 HFO/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.



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### **SUMMARY OF SAFETY AND EFFECTIVENESS**

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

◦ **Comparison with Predicate**

The Signa HFO/i VH/i Magnetic Resonance System is comparable to the Signa Horizon CX and the Signa Profile Magnetic Resonance Systems with the main differences being the 0.7T Open Superconducting Magnet design.

◦ **Summary of Studies**

The Signa HFO/i Magnetic Resonance 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 HFO/i Magnetic Resonance System is comparable to the Signa Horizon CX and the Signa Profile Magnetic Resonance Systems.

◦ **Conclusions**

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Larry A. Kroger, Ph.D.  
Senior Regulatory Programs Manager  
GE Medical Systems, Inc.  
P.O. Box 414, W-709  
Milwaukee, WI 53201

Re: K992746  
Sigma HFO/I Magnetic Resonance System  
Dated: August 13, 1999  
Received: August 16, 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 (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) 594-4613. 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): K99 2746

Device Name: Signa HFO/i Magnetic Resonance System

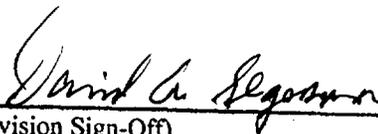
Indications for Use:

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Due to the 'open' design of the system, the HFO/i may also be used 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 K99 2746

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_