

## 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  
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**Date Prepared:** November 4, 2003

### Device Name:

GE 0.35T Signa ®Ovation with Excite Magnetic Resonance System  
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

### Marketed Device:

The GE 0.35T Signa ®Ovation with Excite MR System is substantially equivalent to the currently marketed Signa® 0.35T MFO/i MR System (K002611) with the main differences being an addition of four independent receive channels and an update to the performance of the gradient amplifiers.

### Device Description:

The 0.35T Signa ®Ovation with Excite Magnetic Resonance System is a modification to the 0.35T Signa® MFO/i Magnetic Resonance System (K002611) which utilizes a permanent magnet to acquire 2D single-slice and multi-slice, and 3D volume images. The 0.35T Signa ®Ovation with Excite Magnetic Resonance System features a permanent magnet operating at 0.35T. 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, short scan times, and multinuclear spectroscopy.

### Indications for Use:

The 0.35T Signa ®Ovation with Excite Magnetic Resonance System is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The 0.35T Signa® Ovation with Excite Magnetic Resonance 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 0.35T Signa ®Ovation with Excite Magnetic Resonance 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.

Due to the 'open' design of the system, the 0.35T Signa<sup>®</sup> Ovation with Excite 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 Device:**

The GE 0.35T Signa<sup>®</sup> Ovation with Excite MR System is a modification of the Signa<sup>®</sup> MFO/i MR system (K002611) with the main differences being the addition of Excite Technology and the addition of the improved gradient performance.

**Summary of Studies:**

The 0.35T Signa<sup>®</sup> Ovation with Excite 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 Safety of Magnetic Resonance Equipment for Medical Diagnosis. The 0.35T Signa<sup>®</sup> Ovation with Excite Magnetic Resonance System is comparable to the currently marketed Signa<sup>®</sup> 0.35T Ovation Magnetic Resonance System.

**Conclusion:**

It is the opinion of GE that the 0.35T Signa<sup>®</sup> Ovation with Excite Magnetic Resonance System is substantially equivalent to the Signa<sup>®</sup> 0.35T MFO/i Magnetic Resonance System. Usage of the 0.35T Signa<sup>®</sup> Ovation with Excite Magnetic Resonance System does not result in any new potential hazards.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 25 2003

Larry A. Kroger, Ph.D.  
Senior Regulatory Programs Manager  
GE Medical Systems  
P.O. Box 414, W-400  
MILWAUKEE WI 53201

Re: K033504  
Trade/Device Name: GE 0.35T Signa® Ovation  
with Excite MR System  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance  
imaging system  
Regulatory Class: II  
Product Code: 90 LNH  
Dated: November 4, 2003  
Received: November 5, 2003

Dear Dr. Kroger:

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.

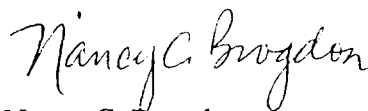
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



STATEMENT OF INTENDED USE

510(k) Number (if known): K03 3504

Device Name: **GE 0.35T Signa® Ovation with Excite MR System**

Indications for Use

The 0.35T Signa® Ovation with Excite Magnetic Resonance System is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Signa 0.35T Signa® Ovation with Excite Magnetic Resonance 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 musculockeletal, vascular, cardiac, and neuro systems. The images produced by the Signa 0.35T Signa® Ovation with Excite Magnetic Resonance 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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David A. Reppert  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K033504

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801-109)

OR

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