



MAY 11 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K950973
Signa Contour
Dated: March 1, 1995
Received: March 2, 1995
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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the 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 may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



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K950973

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SUMMARY OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS

Signa Contour Magnetic Resonance System

1) Indications for Use

The Signa Contour System 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 Contour 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.

2) Device Description

The Signa Contour System utilizes a 0.5T superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. A wide variety of pulse sequences is provided to the operator, including inversion recovery, spin echo, gradient echo, gradient recalled, and steady state, free precession acquisitions. 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. The Signa Contour System can be used as a stationary or mobile system.

3) Marketing History

This product is similar to the Vectra and Signa Advantage MR Systems presently being marketed by GE Medical Systems.

4) Potential Adverse Effects on Health

The operation of the Signa Contour System does not result in any additional potential hazards when compared to previously marketed devices. The potential hazards from MR devices can be summarized as static magnetic field effects, changing magnetic field effects, RF heating, acoustic hazards, unexpected released of cryogen vapor from the magnet and claustrophobia. Warnings concerning these potential hazards are addressed in the product labeling.

5) Conclusions

It is the opinion of GE that the Signa Contour System is substantially equivalent to the Vectra and Signa Advantage MR Systems. The Signa Contour does not include any new indications for use, nor does use of this device result in any new potential hazards.