GE Medical Systems

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

K984167

JAN 12 1999

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, November 19, 1998

- Identification of the Product
  SAGE 7 Spectroscopy Analysis Option

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

- Marketed Devices

  The SAGE 7 Spectroscopy Analysis option is an enhancement to the currently marketed SA/GE Analysis option in distribution since the reclassification of Magnetic Resoncance Diagnostic devices (ref. 53 FR 5078, Feb. 1, 1989).

- Device Description

  The GE SAGE 7 Spectroscopy Analysis Software is designed to operate on GE Signa Horizon Systems and GE Advantage Windows workstations. It provides a toolkit of software applications to handle a wide variety of tasks associated with spectroscopy data management. The SAGE (**S**pectroscopy **A**nalysis **GE**) package provides the capability for the trained clinical spectroscopist to reconstruct, analyze, and display spectra and spectroscopic images to provide information to support a diagnosis. SAGE 7 provides a tool for the spectroscopist to process raw spectroscopy data into spectra or spectroscopic images, view them, and optionally perform numerical analyses to obtain spectroscopic parameters (ex. peak positions, widths, heights, areas, etc.).

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SUMMARY OF SAFETY AND EFFECTIVENESS

- Indications for Use

SAGE 7 is a package of software tools for MR spectroscopic data processing and display. SAGE 7 is indicated for use for a wide variety of MR spectroscopic data management tasks, including file handling, display, processing/modeling, analysis, storage and hard copy output. The resultant spectroscopic presentations, when interpreted by a trained physician, can provide physiological / chemical information that can be useful in determining a diagnosis.

- Comparison with Predicate

The SAGE 7 Spectroscopy Analysis option is an enhancement to the SA/GE Analysis option. The basic operations (ex. Fourier transform, phasing, peak-picking, integration, fitting, etc.) have not significantly changed, and are provided in both SAGE 7 and the SA/GE Analysis option. What has changed is the sophistication of the user interface. In addition, the increased computational capability of modern workstations have made possible as routine operations some sophisticated curve-fitting algorithms that were impractical on older computer hardware.

- Summary of Studies

The SAGE 7 Spectroscopy Analysis option was evaluated to International medical equipment safety standard IEC 601-2-33 titled Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. The SAGE 7 Spectroscopy Analysis option is comparable to the SA/GE Spectroscopy option.

- Conclusions

It is the opinion of GE that the SAGE 7 Spectroscopy Analysis option is substantially equivalent to the SA/GE Spectroscopy option. SAGE 7 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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1999

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

Re: K984167
SAGE 7 Spectroscopy
Dated: November 19, 1998
Received: November 20, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNI

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): K984167

Device Name: SAGE 7 Spectroscopy

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984167

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)