



K972296
GE Medical Systems

SEP 15 1997

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 11, 1997

- Identification of the Product

Signa Profile 9 Inch Coil and Kinematic Positioner Options

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

- Marketed Devices

The Signa Profile MR System with the 9 Inch Coil and the Kinematic Positioner Options are substantially equivalent to the currently marketed Signa Profile System (software and electronics) and the Signa Profile Extremity Coil.

- Device Description

The Profile 9 Inch Coil consists of a linear solenoid coil. It is a split two part design that has a base and a removable top to facilitate patient positioning. It is designed for use with a vertical magnetic field MR imaging system.

The Kinematic Positioner provides support for the legs for MR scanning. It has two usages. One is for a scan when the scanned leg is fixed, and the other is while the scanned leg is moving down.



SUMMARY OF SAFETY AND EFFECTIVENESS

◦ Indications for Use

The Indications for Use for the Signa Profile 9 Inch Diameter Coil and Kinematic Positioner Options expands the capability of the Signa Profile System. The Kinematic Positioner accommodates and improves imaging of the knee and surrounding structures. The 9 inch Coil is intended for imaging of the cervical spine, shoulder, knee and surrounding structures.

◦ Comparison with Predicate

The Profile 9 Inch Surface Coil is similar to the Profile Extremity Coil except that the Extremity coil is a quadrature receive only coil while the 9 inch coil is a linear receive only coil.

◦ Summary of Studies

The 9 Inch Surface Coil was evaluated to the appropriate NEMA performance standards. Both options were evaluated to the International safety standards IEC 601-1 and IEC 601-2-33. Both options performed to stated specifications.

◦ Conclusions

It is the opinion of GE that the Signa Profile System with the 9 Inch Surface Coil and Kinematic Positioner options are substantially equivalent to the presently marketed Signa Profile System and the Signa Profile Extremity Coil. These options do not result in any new potential hazards.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Larry A. Kroger, Ph.D.
Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201Re: K972296
Signa Profile 9-Inch Coil and Kinematic Positioner
Dated: June 11, 1997
Received: June 19, 1997
Regulatory Class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Dr. Kroger:

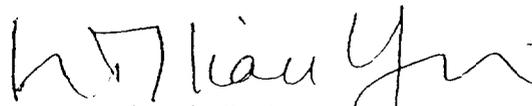
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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/dsmamain.html>.

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

Enclosure

