



K971668

GE Medical Systems

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

JUL 24 1997

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, May 2, 1997
- Identification of the Product
Signa Profile Wrist Coil and Mobile Siting 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 Wrist Coil and the Mobile Siting Options are substantially equivalent to the currently marketed Signa Profile System (software and electronics).
- Device Description
The Signa Profile System is identical for both the Mobile and Fixed Site options. The Wrist Coil option is a quadrature receive only coil. The coil comes with an adjustable positioning base and patient comfort pads for support. It is designed for use with a vertical magnetic field MR imaging system.
- Indications for Use
The Indications for Use for the Mobile Siting option of Signa Profile System is the same as for a Fixed Site System. The Wrist Coil expands the capability of the Signa Profile System. It accommodates and improves imaging of the wrist and surrounding structures.



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Comparison with Predicate

There are no differences between a Signa Profile System when in a Mobile or Fixed site. The Wrist Coil is similar to the Extremity Coil with the biggest difference being in dimensions, the Wrist Coil being smaller.

Summary of Studies

The Wrist Coil and a Mobile Sited Signa Profile System were evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard. Both options performed to stated specifications.

Conclusions

It is the opinion of GE that the Signa Profile System with the Wrist Coil and Mobile Siting options are substantially equivalent to the presently marketed fixed site Signa Profile and the Signa Profile Extremity Coil. These options do not result in any new potential hazards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K971668
Signa Profile Wrist Coil and Mobile Siting Options
Dated: April 30, 1997
Received: May 6, 1997
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

JUL 24 1997

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

510(k) Number (if known): K971668

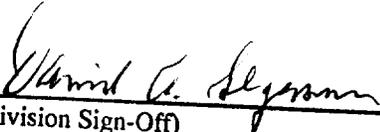
Device Name: Signa Profile Wrist Coil and Mobile Siting Options

Indications For Use:

The Indications for Use for the Mobile Siting option of Signa Profile System is the same as for a Fixed Site System. The Wrist Coil expands the capability of the Signa Profile System. It accommodates and improves imaging of the wrist and surrounding structures.

(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 K971668

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____