2/19/99

K983139

GE Medical Systems

Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of 21CFR Part 807.7(h).

Identification of Submitter

Larry A Kroger, Ph.D.
(414) 544-3894
Summary prepared 4 September 1998

Product Identification

Name: Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil
Manufacturer: General Electric Medical Systems

Predicate Marketed Devices

The Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil is substantially equivalent to the currently marketed products:

- Signa® 1.5T Magnetic Resonance System; 510(k) Number K962061
  This submission cleared the MR system for imaging.
- Hydrogen Spectroscopy Accessory - Probe; 510(k) Number K930265
  This submission cleared the option for the MR system to produce localized spectra that display the internal biochemical characteristics of the human body.
- General Purpose Flex Coil; 510(k) Number K923264
  This submission cleared the use of the flex coil within the MR system as an option for the purpose of improving the signal-to-noise performance of the MR system in specific anatomical areas.

Statement of Indications for Use

The Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil is designed to operate with the Signa® 1.5T Magnetic Resonance System. The coil is simply to improve the signal-to-noise performance of the MR system in specific anatomical areas.

The Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil is intended for general diagnostic use to present magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance of phosphorus (^{31}P) spectra.

Device Description

The coil consists of two 5 inch by 6.5 inch surface coils that are electronically summed to create a co-rotating "saddle-coil" pair. The two coils are contained in a flexible material, covered with fabric. This allows the flex coil to bend in one direction, making it easy to wrap around the anatomy of interest. The unit is 21" long (not including straps) by 8" wide.

Clinical benefits

When the coil pair is aligned properly, this "saddle" design provides uniformity in SNR across the sensitive volume of the coil.

Features

- The Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil consists of two overlapped loop coils with an octogonal shape. The two coils are contained in a flexible foam material with a cleanable coated surface.
- The flexibility of the coil makes it easy to wrap the coil around the anatomy of interest.

- The ^{31}P Flex Coil performs best when closest to a circular shape, and less well when in flatter configuration.
- The coils are 13cm by 16.5cm surface coils that are electronically summed to create co-rotating "saddle" coil pair. When the coil pair is aligned properly, this saddle design provides good uniformity across the senstive volume of the coil.
- The 1.5T Phosphorous (^{31}P) Transmit/Receive Flex Coil is available in configurations for fixed sites and relocatable units.

The subject magnetic resonance surface coil has the same technological characteristics as the legally marketed predicate magnetic resonance surface coils. Specifically, the features, specifications, materials, and mode of action are equivalent.

The above statements are accurate representations of this 510(k) premarket notification and of the device this firm intends to market. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted (21CFR 807.87).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

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

Re: K983139
Phosphorus (P-31) Transmit/Receive Flex Coil for 1.5T Signa MRI System
Dated: December 28, 1998
Received: December 29, 1998
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 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

Indications for Use Statement

510(k) Number (if known): K983139

Device Name: Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil

Indications for Use:

The Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil is intended to operate with the Signa® 1.5T Magnetic Resonance System. The coil is simply to improve the signal-to-noise performance of the MR system in specific anatomical areas.

The Signa® 1.5T Phosphorus (^{31}P) Transmit/Receive Flex Coil is intended for general diagnostic use to present magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance of phosphorus (^{31}P) spectra.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
DRAERD

510(k) Number: K983139

Prescription Use ✓ or Over-The-Counter Use_____
(Per 21CFR801.109) (Optional Format 1-2-96)