K03 0495

510(K) SUMMARY

MAR 0 5 2003

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter:	GE Medical Systems PO Box 414 Milwaukee, WI 53201
Contact Person:	Larry A. Kroger Ph.D. Manager, Regulatory Programs
Telephone:	262- 544-3894
Fax:	262- 548-4768
Date Prepared:	January 31, 2003

Device Name:

3.0T Torso Phased Array Coil
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-MOS

Marketed Device:

The 3.0T Torso Phased Array Coil is substantially equivalent to the currently marketed GE Medical Systems 1.5T Cardiac Phased Array (K971667) and USA Instruments Torso and Pelvis Phased Array Coil (K001209).

Device Description:

The 3.0T Torso Phased Array Coil is a four-channel phased array receive only MR coil used in conjunction with the GE 3.0T MR system.

Indications for Use:

The coil is indicated for use, on the order of a physician in conjunction with a 3.0T MR scanner, as an accessory to produce images of the abdominal and pelvic regions in 2D and 3D.
The primary applications associated with evaluation of the anatomy are as follows:

- Thorax
- Abdomen
- Male and Female Pelvis
- Prostate

Comparison with Predicate Device:

The 3.0T Torso Phased Array Coil is a modification of the GE Medical Systems 1.5T Cardiac Phased Array Coil (K971667) with the main differences being that the 3.0T

Torso Phased Array Coil is tuned to 127.72MHz for operation at 3.0T instead of 63.86MHz for operation at 1.5T. In addition the dimensions of the 3.0T Torso Phased Array Coil (34cm wide and 32cm long) are larger than the dimensions of the 1.5T Cardiac Phased Array Coil for a higher FOV coverage requirement in case of the 3.0T Torso Phased Array coil. The technological similarities to the USA Instruments Torso and Pelvis Phased Array Coil (K001209) include similar applications and indications for use.

Summary of Studies:

Testing was performed to demonstrate that the design of the 4 channel 3.0T Torso Phased Array Coil meet predetermined acceptance criteria.

Conclusion:

It is the opinion of GE that the 3.0T Torso Phased Array Coil is substantially equivalent to the currently marketed GE Medical Systems 1.5T Cardiac Phased Array Coil (K971667) and USA Instruments Torso and Pelvis Phased Array Coil (K001209). Usage of the 3.0T Torso Phased Array Coil does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 5 2003

GE Medical Systems
% Mr. Heinz Joerg Steneberg
TUV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K030495
Trade/Device Name: 3.0T Torso Phased Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: February 14, 2003
Received: February 19, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030495

Device Name: 3.0T Torso Phased Array Coil

Indications For Use:

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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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030495

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