MAY - 2 2003 K03 1230

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
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- Date Prepared:

  March 21, 2003

- Identification of the Product
  Propeller Imaging Option for MRI

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

- Common Name
  Propeller Imaging Option for MRI

- Classification Name
  Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

- Device Description

  The Propeller Imaging Option is a Fast Spin Echo (FSE) based pulse sequence that provides improved signal to noise and contrast to noise compared to traditional FSE with comparable resolution and scan time, and may be used to reduce motion-induced artifacts. With the addition of Diffusion gradients, Propeller may be used to differentiate tissues with restricted diffusion from tissues with normal diffusion, similar to Diffusion Weighted EPI.

- Indications for Use

  When used with diffusion sensitizing gradients on a minimum of 3 axes, it will augment the standard EPI-based diffusion imaging by providing improved image quality in areas of high susceptibility. This may aid the trained physician in the visualization of pathology in areas traditionally obscured by susceptibility artifacts.

  It is intended for use in anatomical regions where significant susceptibility differences exist between adjacent structures (e.g. tissue/air and tissue/bone). This includes, but is not limited to, inferior brain areas such as cerebellum, internal auditory canal,

vertebrae and orthopedic areas. Other high susceptibility regions include tissue in the presence of MRI compatible metallic implants, artificial joints, etc.

When used in the place of high resolution FSE, it will yield improved contrast-to-noise and signal-to-noise with comparable resolution and overall scan time, or improved contrast-to-noise and signal-to-noise with minimal in-plane motion-induced artifact. This may aid the trained physician in visualization of areas with reduced signal and image contrast or areas obscured by motion artifacts.

It is intended for use in high-resolution anatomical regions where FSE is traditionally used, particularly in neurological imaging, where improved contrast-to-noise and signal-to-noise is needed.

- Comparison with Predicate

  The Propeller Imaging Option is substantially equivalent to the features currently marketed GE Medical System Diffusion Weighted EPI Imaging Option (510k #K972990), and Echo Planar Imaging Option including FSE (K944979).

- Summary of Studies

  The Propeller Imaging Option was evaluated to theIEC60601-1-4, the Programmable Electrical Medical Systems standard, and IEC 60601-2-33 International medical equipment safety standard for Magnetic Resonance Systems.

- Conclusions

  It is the opinion of GE that the Propeller Imaging Option for MRI 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

MAY - 2 2003

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

Re: K031230
Trade/Device Name: GE Propeller Imaging Option for MRI
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: April 17, 2003
Received: April 18, 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): K031230

Device Name: GE Propeller Imaging Option for MRI

Indications For Use:

Propeller Imaging Option is a Fast Spin Echo (FSE) based sequence which employs a alternate k-space trajectory.

1. When used with diffusion sensitizing gradients on a minimum of 3 axes, it will augment the standard Echo Planar Imaging (EPI) based diffusion imaging by providing improved image quality in areas of high susceptibility. This may aid the trained physician in the visualization of pathology in areas traditionally obscured by susceptibility artifacts.

It is intended for use in anatomical regions where significant susceptibility differences exist between adjacent structures (e.g. tissue/air and tissue/bone). This includes, but is not limited to, inferior brain areas such as cerebellum, internal auditory canal, vertebrae and orthopedic areas. Other high susceptibility regions include tissue in the presence of MRI compatible metallic implants, artificial joint, etc.

2. When used in the place of high resolution FSE, it will yield improved contrast-to-noise and signal-to-noise with comparable resolution and overall scan time, or improved contrast-to-noise and signal-to-noise with minimal in-plane motion-induced artifact. This may aid the trained physician in visualization of areas with reduced signal and image contrast or areas obscured by motion artifacts.

It is intended for use in high-resolution anatomical regions where FSE is traditionally used, particularly in neurological imaging, where improved contrast-to-noise and signal-to-noise is needed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for NB

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031230

✓

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)