K03 1927

JUL 2 2003

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:
  May 28, 2003

- Identification of the Product
  GE Delta Software Option for MRI

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

- Common Name
  Software Option for MRI

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

- Device Description
  The GE Delta Software Option for MRI is an analytical software application intended to review and analyze medical images.

- Indications for Use
  The GE Delta Software Option for MRI is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. Delta can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows the access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in a cine mode to facilitate visualization.

  A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

  The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

- Comparison with Predicate
  The Delta Option is substantially equivalent to the features in currently marketed MEDIS Medical Imaging Systems FLOW (K994282) and MEDIS Medical Imaging Systems MASS (K994283). Both predicate devices are currently distributed by GE Medical Systems and manufactured by MEDIS.

- Summary of Studies
  The Delta Option was evaluated to the IEC60601-1-4, 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 Delta 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

JUL 2 2003

GE Medical Systems
% Mr. Heinz Joerg Steneberg
Primary Third Party Reviewer
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K031927
Trade/Device Name: GE Delta Software Option for MRI
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: June 19, 2003
Received: June 23, 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): K031927

Device Name: GE Delta Software Option for MRI

Indications For Use:

The GE Delta Software Option for MRI is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. Delta can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows the access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in a cine mode to facilitate visualization.

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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)

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031927