K023943

MAY 0 6 2003

**GE Medical Systems**
3000 N. Grandview Blvd.
Waukesha, WI 53188

# 510(k) 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).

**Submitter** Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (262) 544-3894, FAX: (262) 548-4768
Date Prepared: November 25, 2002

## PRODUCT IDENTIFICATION

Name: CT Colonography

Classification Name: Accessory to Computed Tomography System

Classification Panel 892 - Radiology

Classification Number: 892.1750

Manufacturer : General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Milwaukee, WI

**Marketed Devices** The CT Colonography option (K023943) is substantially equivalent to the device listed below:

| | |
|---|---|
| Model: | CT Colonography/Navigator2 |
| Manufacturer: | General Electric Medical Systems, Milwaukee, WI |
| 510(k) #: | K012313 |

| | |
|---|---|
| Model: | V3D-Colon |
| Manufacturer | Viatronix Inc., Stony Brook, NY |
| 510(k) #: | K020658 |

**Device Description:**
CT Colonography is an image analysis software package that includes all the required software that allows the user to study the inside, wall, and outside of the colon using CT-acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. CT Colonography is an advanced visualization software option that provides endoluminal views of anatomical structures. The flexibility of this software allows the user to move interactively from air paths to inner vessels visualization and thus, it is not limited to inner navigation of structures as lungs and sinuses. Volume Analysis (includes both, CT/MR Windows Workstation, K913770 and 3D & Dentascan for Windows K923077) provides the base for Colonography, CTC/Nav2 and Nav2 alone, which allows an increase in the ease of use and productivity. Colonography, CTC/Nav2 and Nav2 alone, also use some options of Volume Rendering (AW Volume Render Option K972399), which allows the user to quickly isolate structure of interest and render volumetric data in three dimensions.

**Indications for Use :**
CT Colonography is a CT image analysis software package which allows the visualization of 2D and 3D medical image data of the colon derived from DICOM 3.0 compliant CT scans for the purpose of screening of a colon to detect polyps, masses, cancers, and other lesions. It provides functionality for 2D/3D rendering, bookmarking of suspected lesions, synchronized viewing of supine & prone data sets, and an object oriented endoluminal display. In comparison to colonoscopy, this tool has an advantage of depth penetration due its 3D presentation capability. It is intended for use by Radiologists, Clinicians, and referring Physicians to process, render, review, archive, print, and distribute colon image studies.

**Comparison with Predicate:**
CT Colonography is an image analysis software built on Colonography/Navigator2 features that allows the user to study the inside, wall, and outside of the colon using CT acquired helical images. The tool is laid out to facilitate the detection of colonic lesions. The functional features of this package are substantially equivalent to that of the following device:

| Device Name | FDA Clearance Number |
|---|---|
| CT Colonography / Navigator 2 | K012313 |
| V3D-Colon | K020658 |

**Adverse Effects on Health :**
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

**Conclusions:**
The CT Colonography option (K023943) does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT Colonography to be equivalent to those of Colongrapy/Navigator2 (K012313) and V3D-Colon (K020658).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

Mr. Marc Orellou
CT Safety and Regulation Engineer
GE Medical Systems
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K023943
Trade/Device Name: CT Colonography
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: February 26, 2003
Received: February 28, 2003

Dear Mr. Orellou:

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

# STATEMENT OF INTENDED USE

510(k) Number (if known): K023943

Device Name: CT Colonography

## Indications For Use:

CT Colonography is a CT image analysis software package which allows the visualization of 2D and 3D medical image data of the colon derived from DICOM 3.0 compliant CT scans for the purpose of screening of a colon to detect polyps, masses, cancers, and other lesions. It provides functionality for 2D/3D rendering, bookmarking of suspected lesions, synchronized viewing of supine & prone data sets, and an object oriented endoluminal display. In comparison to colonoscopy, this tool has an advantage of depth penetration due to its 3D presentation capability. It is intended for use by Radiologists, Clinicians, and referring Physicians to process, render, review, archive, print and distribute colon image studies.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023943