K041270

MAY 27 2004

GE Medical Systems

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.
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3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: February 20, 2004.

PRODUCT IDENTIFICATION

Name: CT Colonography II

Classification Name: Accessory to Computed Tomography System

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

Distributor: General Electric Medical Systems, Buc, France.

Marketed Devices The CT Colonography II is substantially equivalent to the devices listed below:

Model: CT Colonography
Manufacturer: General Electric Medical Systems, Buc, France
510(k) #: K023943

Device Description:

CT Colonography II 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

Indications for Use:

CT Colonography II 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 the 2D, 3D and 360 dissection views, 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.

Comparison with Predicate:
The functional features of the CT Colonography II software package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
CT Colonography	K023943

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 II 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 II to be equivalent to those of CT Colonography (K023943).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

General Electric Medical System
% Mr. Tamas Borsai
Program Manager 510(k) Review
TUV Rheinland of North America, Inc.
Medical Division, Newton Office
12 Commerce Road
NEWTON CT 06470

Re: K041270
Trade/Device Name: CT Colonography II
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: NWE
Dated: May 3, 2004
Received: May 12, 2004

Dear Mr. Borsai:

This letter corrects our substantially equivalent letter of May 27, 2004.

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 such 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 os 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 this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041270

General Electric Medical Systems

STATEMENT OF INDICATION FOR USE

Device name: CT Colonography II

Indication for Use:

CT Colonography II 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 the 2D, 3D and 360 dissection views, 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

David A. Lepman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041270