



Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVEN PA 19355

December 3, 2014

Re: K140920
Trade/Device Name: syngo.CT Colonography
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: NWE
Dated: October 31, 2014
Received: November 04, 2014

Dear Ms. Mangum:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible behind the signature.

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140920

Device Name
syngo.CT Colonography

Indications for Use (Describe)

syngo.CT Colonography is used for easy-to-perform and efficient inspection of the colonic surface. It facilitates the search and diagnosis of colon lesions. The workflow management ensures that the required data and tools are offered to you according to your role and task.

syngo.CT Colonography is a clinical post-processing workflow for basic virtual colonoscopy. It is designed to support the following image reconstruction techniques:

- Multiplanar Reconstruction (MPR)
- Volume Rendering Technique (VRT)
- Perspective surface shaded display (pSSD)

The following evaluation tools are provided with this workflow:

- Virtual Flight
- Panoramic View
- Polyp Lens
- Stool Tagging • Stool Subtraction
- Polyp Enhanced Viewing (PEV)
- Movie

syngo.CT Colonography supports reporting with appropriate reporting tools such as lesion location, lesion characterization, and key image creation. Combining enhanced commercially available digital image processing tools with an optimized workflow and reporting tools, the software is designed to support the physician on confirming the presence or absence of physician identified colon lesions (for example, polyps) in addition to evaluation, documentation, and follow-up of any such lesions using standard or low-dose spiral CT scanning.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) SUMMARY
FOR
syngo.CT Colonography**

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Date Prepared: October 30, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. General Information

Importer/Distributor:

Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:

2240869

Manufacturing Site:

Siemens AG Medical Solutions
Henkestraße 127
D-91052 Erlangen, Germany

Establishment Registration Number:

3002808157

2. Contact Person:

Mrs. Kimberly Mangum
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 448-1772 Fax: (610) 448-1778
Email: kimberly.mangum@siemens.com

3. Device Name and Classification

Product Name: syngo.CT Colonography
Propriety Trade Name: syngo.CT Colonography
Classification Name: Colon Computed Tomography System,
Computer Aided Detection
Classification Panel: Radiology
CFR Section: 21 CFR §892.2050
Device Class: Class II

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Product Code: NWE

Legally Marketed Predicate Devices

Trade Name: syngo Colonography – Software Package with Extended Functionality

510(k): K042605

Clearance Date: October 08, 2004

Classification Name: Colon Computed Tomography System, Computer Aided Detection

Classification Panel: Radiology

Classification Regulation: 21 CFR § 892.2050

Device Class: II

Product Code: NWE

4. Substantial Equivalence

The subject device syngo.CT Colonography is substantially equivalent to following medical devices in commercial distribution:

<i>Predicate Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>
Colonography Software Package with extended functionality	K042605	10/08/2004

5. Device Description

syngo.CT Colonography is a self-contained image analysis software package for evaluating CT volume data sets. The software is designed to support the physician in studying the inside, wall, and outside of the colon. It helps the physician to classify conspicuous regions of tissue with respect to their size, shape, and position.

Therefore, it combines tools for

- visualization of the data:
 - a) Panoramic Endoluminal View
 - b) Stool Tagging
 - c) Workflow Improvements
 - d) Virtual Dissection
 - e) Polyp Lens
 - f) Stool Subtraction
- navigation through the CT volume data sets
- evaluation of potential findings:
 - a) Semi-automatic measurements
- reporting of results:
 - a) Movie

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For the inspection of the colonic surface and diagnosis of colon lesions clinically, two workflows have been established:

- ***2-dimensional search and 3-dimensional diagnosis:***
Multiplanar Reconstructions (MPRs) are used for the detection of lesions. If a suspicious structure has been detected, the virtual endoscope is located and the final diagnosis can be performed.
- ***3-dimensional search and 2-dimensional diagnosis:***
A virtual flight is performed starting at the rectum position of one data set. If a suspicious structure has been detected, the final diagnosis is performed using the MPRs.

6. Comparison of Technological Characteristics with the Predicate Device

syngo.CT Colonography is a post processing application operating on the multi-user syngo.via client server platform. The subject device syngo.CT Colonography provides similar evaluation, processing, reporting and visualization tools, and functionality as the predicate device syngo Colonography with extended functionality (K042605, clearance date October 8, 2004). This includes various image processing and visualization. At a high level, the subject and predicate devices are based on the following same technical elements:

- Polyp Enhanced Viewing
- Segmentation in Global View
- Size measurements of polyps
- 3D Inspection of colon in Endoluminal view

The subject device contains additional automatic and semi-automatic visualization and evaluation tools which support assessment of colonic lesions. syngo.CT Colonography does not have significant changes in technological characteristics when compared to the predicate devices. The indication for use, intended use, operating principle, and fundamental scientific technology are similar; therefore, Siemens believes that syngo.CT Colonography is substantially equivalent to the predicate devices.



7. Performance Data

Nonclinical Testing:

syngo.CT Colonography is designed to fulfill the requirements of the following safety and performance standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
12-238	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.18	03/16/2012	NEMA
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO
5-85	General	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability	60601-1-6 Edition 3.0 2010-01	1/30/2014	IEC
5-41	General	Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4:2000, Consol. Ed. 1.1		IEC

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non clinical tests (integration and functional) were conducted for the syngo.CT Colonography during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Software Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for

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Software Contained in Medical Devices” issued on May 11, 2005 is also included as part of this submission.

Clinical Testing:

Clinical performance tests were conducted to demonstrate performance, safety, and effectiveness of syngo.CT Colonography. Testing was provided to cover a variety of clinical situations that would be seen in daily clinical use of the subject device.

Summary:

Performance tests were conducted to test the functionality of the syngo.CT Colonography post processing application. These tests have been performed to test the ability of the included features of syngo.CT Colonography. The results of these tests demonstrate that this application is able to inspect the colonic surface and colon lesions. Furthermore, clinical performance testing information was provided to demonstrate the functionality of supported application features.

The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

8. Indications for Use

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polyps) in addition to evaluation, documentation, and follow-up of any such lesions using standard or low-dose spiral CT scanning.

9. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence

In summary, Siemens is of the opinion that the syngo.CT Colonography does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.