

APR 07 2014

**510(k) SUMMARY**  
**FOR**  
**syngo® Dual Energy Software Package**

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

Date Prepared: August 9, 2013

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

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**3. Device Name and Classification**

**Product Name:** syngo® Dual Energy Software Package  
**Propriety Trade Name:** syngo® Dual Energy Software Package  
**Classification Name:** Computed Tomography X-ray System  
**Classification Panel:** Radiology  
**CFR Section:** 21 CFR §892.1750  
**Device Class:** Class II  
**Product Code:** 90JAK

**Legally Marketed Predicate Devices**

**Trade Name:** syngo® Dual Energy  
**510(k)#:** K062351  
**Clearance Date:** October 5, 2006  
**Classification Name:** System, X-Ray, Tomography, Computed  
**Classification Panel:** Radiology  
**Classification Regulation:** 21 CFR § 892.1750  
**Device Class:** II  
**Product Code:** JAK

**Trade Name:** syngo® Dual Energy with extended functionality  
**510(k)#:** K083524  
**Clearance Date:** April 01, 2009  
**Classification Name:** System, X-Ray, Tomography, Computed  
**Classification Panel:** Radiology  
**Classification Regulation:** 21 CFR § 892.1750  
**Device Class:** II  
**Product Code:** JAK

**4. Substantial Equivalence:**

The subject device Kidney Stones application class included as part of Siemens syngo® Dual Energy software package is substantially equivalent to the Kidney Stone application classes included as part of the following medical devices in commercial distribution:

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
syngo® Dual Energy Software Package	K083524	April 1, 2009
syngo® Dual Energy	K062351	October 5, 2006

**5. Device Description:**

syngo® Dual Energy Software Package is a post processing application package consisting of the following applications that can be used to improve visualization of various energy dependent materials in the human body:

- Lung Nodules
- Xenon (Lung Ventilation)
- Monoenergetic
- Brain Haemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Dual Energy Bone Removal
- Cartilage, Tendon, Ligament
- Lung Perfusion
- Liver
- Hard Plaques in Vessels
- Kidney Stones

The output of the syngo® Dual Energy Software Package applications are shown within three orthogonal slices (sagittal, coronal, and axial) as overlay to anatomical grayscale information. Typically the anatomical information is built from a combination of the original dual energy scans (for example 80kV and 140kV or 100 kV and 140kV and/or by using different filters).

Window values, color look-up tables (LUTs) and masking operations for both datasets (anatomical and the material decomposition information) can be interactively defined and user modified. An additional side-by-side display of Dual Energy results is also supported, and navigation and rotation of datasets are provided.

After two series of dual energy images have been loaded from the patient browser (80kV and 140kV or 100 kV and 140kV), three orthogonal slices (sagittal, coronal, and axial) of both spectra are shown within the respective segments on the monitor in grayscale mode. The middle axial, sagittal and coronal view is used for the initial display.

The Kidney Stones application class is a post processing application that uses dual energy information to visualize the chemical composition in kidney stones. The basis for this approach is a material decomposition into tissue, uric acid, and oxalate stones. The result of material decomposition is shown as a color overlay to anatomical gray scale information.

## **6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**

The Kidney Stones application class is a post processing application included as part of syngo® Dual Energy Software Package. syngo® Dual Energy Software Package is a post processing application package embedded in the frame-work of a single user HW/SW architecture based on advanced workstations.

The predicate device Kidney Stones application class is a post processing application which was cleared as part of syngo® Dual Energy Software (K062351, clearance date October 5, 2006) and syngo® Dual Energy with extended functionality (K083524, clearance date April 1, 2009). The subject device Kidney Stones application class provides similar evaluation,

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reporting and visualization tools, and functionality as the predicate devices Kidney Stones application classes.

This includes image processing and visualization tools such as basic visualization of various energy dependent materials in the human body and VRT visualization. The subject device Kidney Stones application class does not have significant changes in technological characteristics when compared to the predicate devices Kidney Stones application class. The Indication for Use, operating principle, and the scientific technology are similar; therefore, Siemens believes that Kidney Stones application class marketed as part of the syngo® Dual Energy Software Package is substantially equivalent to the predicate devices. No other post processing applications cleared as part of the predicate devices have been modified with this submission.

**7. Nonclinical Testing:**

syngo® Dual Energy Software Package is designed to fulfill the requirements of following standards:

- IEC 60601-1-6 : 2007; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 Ed. 1.0, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2009 DICOM conformity is fully covered by syngo.via implementations.

Non clinical tests were conducted for the Kidney Stones Application class during product development. Phantom based test were conducted using kidney stones of various chemical composition and sizes. The stones were put into cylindrical phantoms with varying diameters and scanned. Classification performance was measured as a function of  $CTDI_{vol}$ , and performance limitations for small or multicomponent stones are a result of the analysis.

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 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.

**8. Indications for Use:**

syngo® Dual Energy is designed to operate with Siemens Dual Source CT scanners. CT images taken at the same time, using two different kV levels, of the same anatomical region of a patient are used. Depending on the region of interest, contrast agents may be used. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. The images are combined to visualize and analyze information about anatomical and pathological structures.

The functionality of the syngo® Dual Energy applications are as follows:

- Lung Nodules
- Xenon (Lung Ventilation)
- Monoenergetic
- Brain Haemorrhage
- Gout Evaluation
- Lung Vessels
- Heart PBV
- Dual Energy Bone Removal
- Cartilage, Tendon, Ligament
- Lung Perfusion
- Liver
- Hard Plaques in Vessels
- Kidney Stones

Kidney Stones is designed to support the visualization of the chemical composition of kidney stones and especially the differentiation between uric acid and non-uric acid stones. For full identification of the kidney stone additional clinical information should be considered such as patient history and urine testing. Only a well-trained radiologist can make the final diagnosis under consideration of all available information. The accuracy of identification is decreased in obese patients.

**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® Dual Energy Software Package does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WD66-G609  
Silver Spring, MD 20993-0002

April 7, 2014

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

Re: K132902  
Trade/Device Name: syngo<sup>®</sup> Dual Energy Software Package  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: March 5, 2014  
Received: March 7, 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,



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)  
K132902

Device Name

syngo® Dual Energy

Indications for Use (Describe)

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The functionality of the syngo® Dual Energy applications are as follows:

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- Gout Evaluation
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- Heart PBV
- Dual Energy Bone Removal
- Cartilage, Tendon, Ligament
- Lung Perfusion
- Liver
- Hard Plaques in Vessels
- Kidney Stones

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

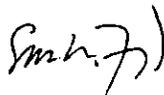
Prescription Use (Part 21 CFR 801 Subpart D)

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

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



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