DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Siemens Medical Solutions, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
51 Valley Stream Parkway, Mail Code D02
MALVERN PA 19355

November 13, 2014

Re: K133643
Trade/Device Name: syngo.CT Liver Analysis
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 4, 2013
Received: November 5, 2013

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,

Robert A Ochs

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133643

Device Name
syngo.CT Liver Analysis

Indications for Use *(Describe)*
syngo.CT Liver Analysis is an image analysis software for CT volume data sets. It analyses the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver. These regions can be evaluated by exploring the volume of the liver and its vascular territories.

Using syngo.CT Liver Analysis, you can evaluate the liver volume and examine the vessels of the liver.
The following evaluation tools are provided:
• Computation and manual correction of liver volumes
• Computation and manual correction of tumor volumes and extent
• Computation and manual correction of liver vessel tree structure
• Computation of territories based on vessel branches
• Tumor position in relation to vessels (i.e. 3D visualization of liver, tumor and vessels)
• Manual definition of separation plane proposals
• Computation of volume of liver parts
• Combination of information from different CT and MR phase volumes

syngo.CT Liver Analysis facilitates reporting by using of appropriate reporting tools, for example, volume statistics and key image creation.
You can use syngo.CT Liver Analysis to create a DICOM Structured Report.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY
FOR
SYNGO.CT LIVER ANALYSIS

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Date Prepared: November 7, 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 Establishment:
Registration Number: 2240869
Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

Manufacturing Facility:
Siemens AG; Medical Solutions
Henkestraße 127
D-91052 Erlangen, Germany
Establishment Registration Number:
3002808157

2. Contact Person:

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Technical Specialist, Regulatory Affairs Submissions
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Malvern, PA 19355-1406
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3. Device Name and Classification

Product Name: syngo.CT Liver Analysis
Propriety Trade Name: syngo.CT Liver Analysis
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: 90JAK

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4. **Legally Marketed Predicate Device:**
Product Name: IQQA Liver Software
Propriety Trade Name: IQQA Liver Software
Classification Name: Picture Archiving and Communications System
Classification Panel: Radiology
CFR Section: 21 CFR §892.2050
Device Class: Class II
Product Code: LLZ

Product Name: syngo.CT Oncology
Propriety Trade Name: syngo.CT Oncology
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

5. **Indications for Use:**
syngo.CT Liver Analysis is an image analysis software for CT volume data sets. It analyses the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver. These regions can be evaluated by exploring the volume of the liver and its vascular territories.

Using syngo.CT Liver Analysis, you can evaluate the liver volume and examine the vessels of the liver.

The following evaluation tools are provided:

- Computation and manual correction of liver volumes
- Computation and manual correction of tumor volumes and extent
- Computation and manual correction of liver vessel tree structure
- Computation of territories based on vessel branches
- Tumor position in relation to vessels (i.e. 3D visualization of liver, tumor and vessels)
- Manual definition of separation plane proposals
- Computation of volume of liver parts
- Combination of information from different CT and MR phase volumes

syngo.CT Liver Analysis facilitates reporting by using of appropriate reporting tools, for example, volume statistics and key image creation.

You can use syngo.CT Liver Analysis to create a DICOM Structured Report.

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6. Substantial Equivalence:

Siemens syngo.CT Liver Analysis post processing software package is substantially equivalent to the following medical devices in commercial distribution as listed in **Table 1**:

Table 1: Predicate Devices

Manufacturer	Predicate Device	510(k) #	Clearance Date
EDDA	IQQA-Liver Software	K061696	November 13, 2006
Siemens	syngo.CT Oncology Software Package	K071310	June 08, 2007

7. Device Description

syngo.CT Liver Analysis is an image analysis software for CT volume data sets. It analyses the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver. These regions can be evaluated by exploring the volume of the liver and its vascular territories. The syngo.CT Liver Analysis Software is designed to operate on the most recent syngo.via platform.

The task is organized as a linear workflow providing the following task steps (several task steps can be skipped to allow fast processing in cases with limited clinical needs):

- **Assignment of CT phase volumes relevant for anatomical information**
  The user has to decide which anatomical structures need to be evaluated and on which CT series the necessary structures have to be segmented. To assign a CT series to an anatomical structure, the user has to drag and drop a series from the Series Navigator on the anatomical series segment. Wrongly assigned series can also be unassigned if needed. For up to 6 anatomical structures, a proper selection of phase volumes is requested:

  1. liver (LIV)
  2. tumor (TUM)
  3. portal vein (PV)
  4. hepatic vein (HV)
  5. hepatic artery (HA) and
  6. bile ducts (BD) or MR data (view only).

- **Manual rigid registration of CT phase volumes**
  In case more than one CT (or MR) series has been selected, the series have to be manually aligned to each other to match up the liver anatomy, using the manual alignment tool.

- **Automatic segmentation of liver, interactive manual correction of result**
  An automatic segmentation of the liver can be corrected interactively. The outer contour of the liver is displayed. For correcting the automatic segmentation, the user can draw splices where the contour of the segmentation needs to be

aligned. Two tools are available to propagate the splices to the liver segmentation.

1. 2D splicing – the contour will follow the newly drawn splices on the given slice only. This option gives full control for complex changes.
2. 3D splicing – the contour will follow the newly drawn splices and is propagated to neighboring slices. This option is recommended for simple changes to have less correction steps.

- **Semi-automatic segmentation of lesions, interactive manual correction of result**
  Multiple lesions can be segmented. All lesions will be listed in the Findings Navigator with name and given volume. To start an initial segmentation, a stroke has to be drawn across the lesion at its largest extent. A 3D segmentation is now computed automatically. To correct the given contour of a lesion, the 3D splicing tool introduced in the liver segmentation step can be used.

- **Semi-automatic segmentation of vasculature, interactive manual correction of result**
  Up to four vascular objects can be segmented in this task step. The initial segmentation is performed by setting a seed point into the corresponding main vessel entering the liver. The system now automatically starts to segment the whole intrahepatic vascular object. In case many vessels have been misleadingly added, a cut off value can be adjusted interactively. Some vessels still might be missed or misleadingly added by the initial segmentation. To correct this, the user can manually add or delete vessels. By moving the mouse cursor over a subtree of the vascular object, the whole subtree is high-lighted for easier exploration of the segmented structures. This is giving a preview of which subtree would be deleted or reclassified by the corresponding tool. The following tools are available for this feature:

  1. Single click add – The user can add additional vessel by setting one seed point into the missing vessel in any orthogonal view in “local” mode.
  2. Multi click add – The user starts segmenting a vascular branch by setting one or more seed points into a missing vessel. After setting the first seed point, an interactive line will show where the course of the newly added vessel would be. The last seed point has to be set by making a double click.
  3. In cases where HV and PV need to be separated from each other, the tools for adding HV or PV vessels can be used to correct the classification of the vessels. Delete – Any vessel or vessel subtree can be deleted by using the deletion tool.

- **Manual anatomical classification of vascular objects, calculation and visualization of vascular territories**
  The vascular territories can be calculated based on the segmentation of the vascular objects. The calculation will be based on an anatomical labeling of the vascular structure which is provided by the user. The user has to label the subtrees of the segmented vascular objects. Each label also has a predefined

color. By moving the mouse cursor over a subtree of the vascular object, the whole subtree is high-lighted. This is giving a preview of which subtree would be colored with the corresponding label. Up to 16 labels can be selected. After all necessary vascular subtrees have been labeled; calculation and visualization of vascular territories can be started.

- **Interactive definition of parts of the liver and calculation of partial volumes**
  The user can inspect the results and interactively define up to three independent separation proposals. A separation proposal can be defined by drawing a contour in one of the orthogonal views or on the 3D liver surface in the VRT segment. After that, two tools are provided to interpolate a separation surface through the given contours. The separation surface can be further adapted by the user by deforming or smoothing it.

- **Inspection of results (2D/3D):**
  At any time the segmented structures and separation surfaces can be reviewed in orthogonal 2D displays and 3D displays. Safety margin around given tumors can also be displayed in 2D and 3D. The margin size can be chosen interactively.

- **Reporting**
  All findings generated by the user as well as calculated volumes and 3D images of the structures are summarized in one report.

8. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

syngo.CT Liver Analysis application is designed to be operated on the syngo.via platform in a single or multi user environment. syngo.CT Liver Analysis software package provides the same evaluation tools and functionality as the predicate devices. syngo.CT Liver Analysis does not have significant changes in technological characteristics when compared to the predicate devices. The intended use is the same and the scientific technology is similar; therefore Siemens believes that syngo.CT Liver Analysis is substantially equivalent to the predicate devices**. Table 2** below provides a comparison of the main features of syngo.CT Liver Analysis in comparison to the predicate devices.

Table 2: Summary of Differences between Subject Device and Legally Marketed Predicate Devices

Property	syngo.CT Liver Analysis	IQQA Liver Software	Syngo CT Oncology Package
Organ Segmentation	Pre-Processing for complete liver segmentation and manual corrections of liver segmentation.	Interactive segmentation of the liver.	N/A

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Property	syngo.CT Liver Analysis	IQQA Liver Software	Syngo CT Oncology Package
Lesion Segmentation	Semi-automated segmentation of liver lesions.	Interactive segmentation of lesions.	Segmentation and volumetric evaluation of suspicious lesions including dedicated tools for lung, liver and lymph node assessment.
Segmentation of Tubular Structures	Semi-automated segmentation of arterial, portal venous and venous vascular bile ducts tree.	Interactive segmentation of vascular structures.	N/A
Organ Territories	3D semi-automated mapping of vascular territories onto liver tissue.	Interactive segmentation of liver segments.	N/A
Organ Separation	Virtual separation planes and subsequent volumetric calculation of liver parts.	Virtual separation planes and subsequent volumetric calculation of liver parts.	N/A
Primary Organ Displayed	Liver	Liver	lesions with focus on lung, liver and lymph nodes

9. Nonclinical Testing:

syngo.CT Liver Analysis is designed to fulfill the requirements of following standards:

- IEC 60601-1-6: 2006; 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: 2008DICOM conformity is fully covered by syngo.via implementations.

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

To ensure performance of the semi-automatic segmentation algorithm, the algorithms were tested on clinical data sets. The datasets used were based on variations that can appear for a given anatomic structure.

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

Summary
Performance tests were conducted to test the functionality of the syngo.CT Liver Analysis post processing application. These tests have been performed to test the ability of the included features of syngo.CT Liver Analysis. The results of these tests demonstrate that this application performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

10. 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.

11. Conclusion as to Substantial Equivalence:
The syngo.CT Liver Analysis has a similar indication for use as the predicate devices. syngo.CT Liver Analysis is an image analysis software for CT volume data sets. It analyses the liver and its intrahepatic vessel structures to identify the vascular territories of sub-vessel systems in the liver. These regions can be evaluated by exploring the volume of the liver and its vascular territories, patient radiology images, or data by the clinician using the same functionalities as the cleared predicate.

It is Siemens opinion, that the syngo.CT Liver Analysis Software is substantially equivalent to the predicate devices listed in **Table 1**. The modifications included in the comparison table and described throughout this submission do not alter the Intended use or fundamental scientific technology of the legally marketed predicate devices. The differences between the legally marketed predicate devices and the subject device have been assessed via Verification and Validation as well as Risk Management. Any differences in technological characteristics are accompanied by information within this submission that demonstrates the device is as safe and effective as the predicate devices and do not raise different questions of safety and effectiveness than the predicate.