Siemens Medical Solutions USA, Inc.
% Alaine Medio
Regulatory Affairs Professional
810 Innovation Drive
KNOXVILLE TN 37932

April 30, 2021

Re: K203699
Trade/Device Name: syngo.CT Extended Functionality
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: March 29, 2021
Received: March 30, 2021

Dear Alaine Medio:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203699

Device Name
syngo.CT Extended Functionality

Indications for Use *(Describe)*
syngo.CT Extended Functionality is intended to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners, and possibly other medical imaging modalities (e.g. MR scanners).

An interface shall enable the connection between the syngo.CT Extended Functionality software package and the interconnected CT Scanner system.

Resulting images created with the syngo.CT Extended Functionality software package can be used to assist trained technicians or physicians in diagnosis.

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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K203699

510(K) SUMMARY

FOR

SYNGO.CT EXTENDED FUNCTIONALITY

I. Identification of the Submitter

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number
2240869

Manufacturing Site
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Siemensstr 1
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Establishment Registration Number
3004977335

Submitter Contact Person:
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Email: alaine.medio@siemens-healthineers.com

II. Device Name and Classification

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

III. Predicate Device

Primary Predicate Device

Trade Name:	syngo.CT Extended Functionality
510(k) Number:	K192402
Clearance Date:	09/20/2019
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Secondary Predicate Device

Trade Name:	AI-Rad Companion (Pulmonary)
510(k) Number:	K183271
Clearance Date:	07/26/2019
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Reference Device

Trade Name:	syngo.CT Pulmo 3D
510(k) Number:	K123540
Clearance Date:	08/29/2013
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

IV. Device Description

syngo.CT Extended Functionality is a software bundle that offers tools to support special clinical evaluations. The “tools” are represented by the so-called Extensions. syngo.CT Extended Functionality can be used to create advanced visualizations and measurements on clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners or other medical imaging modalities (e.g. MR scanners) by using the Extensions. Advanced visualizations and measurements are listed as follows. The subject device in the current software version SOMARIS/8 VB51 has been extended by the Extension Pulmonary Density.

This feature provides the possibility to segment opacity regions of CT images of the lungs using an AI algorithm. Pulmonary Density counts image voxels inside opacity regions and calculates the percentages of these voxels relative to the total number of voxels per lobe, lung and in total. Afterwards, each of the five lung lobes is assigned a score ranging from 0 to 4 based on the percentage of opacity as follows: 0 (0%), 1 (1%–25%), 2 (26%–50%), 3 (51%–75%), or 4 (76%–100%). Then a summation of the five lobe scores (range of possible scores, 0–20) are generated in the device outputs.

V. Indications for Use

syngo.CT Extended Functionality is intended to provide advanced visualization tools to prepare and process medical images for diagnostic purpose. The software package is designed to support technicians and physicians in qualitative and quantitative measurements and in the analysis of clinical data that was acquired and reconstructed by Computed Tomography (CT) scanners, and possibly other medical imaging modalities (e.g. MR scanners).

An interface shall enable the connection between the syngo.CT Extended Functionality software package and the interconnected CT Scanner system.

Resulting images created with the syngo.CT Extended Functionality software package can be used to assist trained technicians or physicians in diagnosis.

VI. Comparison of Technological Characteristics with the Predicate Device

The differences and similarities between the above referenced predicate device are listed at a high-level in the following table:

Feature	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**
	syngo.CT Extended Functionality *(SOMARIS/8 VB51)*	syngo.CT Extended Functionality *(SOMARIS/8 VB40)*	AI-Rad Companion (Pulmonary) *(VA10)*
1. Pulmonary Density			
- *Segmentation of Lung*	Creation of a lung segmentation mask by combining the segmentation masks of 5 lung lobes. **The same algorithm as cleared with the secondary predicate device has been trained with more data.**	N/A	The device's algorithm creates a lung segmentation mask by combining the segmentation masks of 5 lung lobes.
- *Segmentation of Lobes*	Computation of segmentation masks of the five lung lobes (right upper (RUL), right middle (RML), right lower (RLL), left upper (LUL) and left lower (LLL) lobe) for a given CT data set of the chest. **The same algorithm as cleared with the secondary predicate device has been trained with more data.**	N/A	Computation of segmentation masks of the five lung lobes (right upper (RUL), right middle (RML), right lower (RLL), left upper (LUL) and left lower (LLL) lobe) for a given CT data set of the chest.
- *Opacity Detection*	AI-based identification of areas with elevated Hounsfield values. Threshold-based identification of highest elevated Hounsfield values inside these elevated regions, by a predefined threshold of -200 HU.	N/A	Secondary predicate device (AI-Rad Companion (Pulmonary)): Identification of areas with lower Hounsfield values inside both lungs in comparison to a predefined threshold of -950 HU.

Feature	Subject Device	Primary Predicate Device	Secondary Predicate Device
	syngo.CT Extended Functionality *(SOMARIS/8 VB51)*	syngo.CT Extended Functionality *(SOMARIS/8 VB40)*	AI-Rad Companion (Pulmonary) *(VA10)*
	Equivalent to the reference device syngo.CT Pulmo 3D (K123540): the areas of elevated Hounsfield values are found by the deep learning approach as described above instead of threshold-based. **The threshold-based segmentation of high opacity regions is same to the parenchyma analysis already cleared with the predicate device AI-Rad Companion Pulmonary (K183271) and syngo.CT Pulmo 3D (K123540).**		Reference device (syngo.CT Pulmo 3D): Pulmo 3D: Identification of areas with lower or elevated Hounsfield values inside both lungs in comparison to a predefined threshold.
- *Measurement Results*	Lung lesion, lung parenchyma, and pulmonary density measurements (output). **The Measurement results are unchanged with the exception of displaying the Pulmonary Density measurements.**	N/A	Lung lesion, lung parenchyma measurements (output).
2. Oncology Extension	The oncology extension offers tools for localization and evaluation of nodules supporting the following main functionalities • Orthogonal measurements of maximum length and width of anatomical structures • Navigation Tool for LungCAD results • Lung Lesion Segmentation **Minor modifications to the Oncology Extension were made.**	The oncology extension offers tools for localization and evaluation of nodules supporting the following main functionalities • Diameter and WHO Area • Lung CAD Series • Lung Lesion Segmentation	AI-Rad Companion (Pulmonary) offers tools for localization and evaluation of nodules supporting the following main functionalities • Lung CAD Series • Lung Lesion Segmentation

The remaining functions in Syngo.CT Extended Functionality remain unchanged compared to the predicate version.

- Interactive Spectral Imaging - Display different representations of Dual Energy data.
- Vascular Extensions - The user can perform a vascular evaluation supporting the following main functionalities: Measuring vessels, Creating DICOM snapshots or result series for

documenting findings and Working on images that are acquired with CT or MR scanner systems constituting one or more volumes of vascular structures

- Osteo Extension - Evaluation of Bone Mineral Density (BMD) values (mg CA-HA/ml).
- Neuro DSA Extension - Selective bone removal from a CT angiography dataset
- ROI HU Threshold Extension – Evaluation of HU Value distributions
- Dual Energy Extension – Simultaneous evaluation for low and high kV dual energy images
- Endoscopic Viewing Extension – Interactive fly through tubular structures that are filled by either low-intensity or high-intensity material
- General (Extension Independent features) – Multiphase support for merged 4D series and editing tool for pre-generated results.

The core modification of the subject device as compared to its predicate device (syngo.CT Extended Functionality (SOMARIS/8 VB40)) is the new feature Pulmonary Density.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

This submission contains performance tests (Non-clinical test reports) to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT Extended Functionality during product development. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Clinical Evaluation of the AI-based Algorithms

Clinical Data Based Software Validation

To validate the syngo.CT Extended Functionality clinical workflow, the following algorithms underwent a scientific evaluation:

- Segmentation of lung lobes
  The lung lobe segmentation algorithm computes segmentation masks of the five lung lobes (right upper (RUL), right middle (RML), right lower (RLL), left upper (LUL) and left lower (LLL) lobe) for a given CT data set of the chest.

- Identification of opaque regions (AI-based)
  The algorithm computes masks of opaque regions in the lung for a given CT data set of the chest. The opaque regions include ground glass opacities, consolidations, and crazy-paving patterns. The calculation is done for each lobe as well as for the complete lung.

For each algorithm of syngo.CT Extended Functionality the analysis is structured as follows:

- Algorithm Description: purpose, functionality, technical description
- Data
  - Training cohort: size and properties of data used for training
  - Description of ground truth / annotations generation

    - Validation cohort: size and properties of data used for testing/validation
- Performance
    - Choice of performance metric
    - Actual performance results
    - Assessment of clinical relevance of achieved performance
- Related clinical research, e.g. publications (if applicable)

The results of clinical data-based software validation for the subject device syngo.CT Extended Functionality demonstrated equivalent performance in comparison to the secondary predicate device for segmentation and lung parenchyma categorization. A complete scientific evaluation report is provided in support of the device modifications.

Performance of lung lobe segmentation of syngo.CT Extended Functionality device has been validated using 250 datasets from multiple sites across the US and Europe. Average DICE coefficients ranged from 0.94 to 0.96.

Performance of the segmentation of opaque regions of syngo.CT Extended Functionality device has been validated using 150 datasets from multiple sites across the US and Europe. Inter-reader-variability of the percentage of opacity (PO) was assessed on a lung lobe level and 95%-Limits of Agreement (LoA) were established. The algorithm performance was compared against the human reads and 93.0% of the PO values were found within the LoA.

Additional analysis was performed for both population-specific subgroups and various technical parameters and consistent performance has been found for both algorithms across all subgroups.

Risk Analysis

The risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support 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.

Siemens hereby certifies that syngo.CT Extended Functionality will meet the following voluntary standards covering electrical and mechanical safety listed below, prior to introduction into interstate commerce:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)/A1:2016	01/14/2019	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	06/27/2016	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	12/23/2016	IEC

VIII. Conclusion

syngo.CT Extended Functionality has the same intended use and same indication for use as the primary predicate device. The technological characteristics such as image visualization, operating platform, and image measurement are the same as the predicate devices.

For the subject device, syngo.CT Extended Functionality, Siemens used the same testing with the same workflows as used to clear the primary predicate device. Siemens considers syngo.CT Extended Functionality to be as safe, as effective, and with performance substantially equivalent to the commercially available predicate devices.