July 19, 2023

Siemens Healthcare GmbH
% Abhineet Johri
Regulatory Affairs Manager
Siemensstr. 1
Forchheim, 91301
GERMANY

Re: K231157
Trade/Device Name: syngo.CT Lung CAD (Version VD30)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: OEB
Dated: June 28, 2023
Received: June 30, 2023

Dear Abhineet Johri:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological Imaging
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OHT8: Office of 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)*

K231157

Device Name
syngo.CT Lung CAD (Version VD30)

Indications for Use *(Describe)*

syngo.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid pulmonary nodules during review of multi-detector computed tomography (MDCT) from multivendor examinations of the chest. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may be otherwise overlooked.

The syngo.CT Lung CAD device may be used as a concurrent first reader followed by a full review of the case by the radiologist or as second reader after the radiologist has completed his/her initial read.

The syngo.CT Lung CAD device may also be used in "solid-only" mode, where potential (or suspected) sub-solid and/or fully calcified CAD findings are filtered out.

The software device is an algorithm which does not have its own user interface component for displaying of CAD marks. The Hosting Application incorporating syngo.CT Lung CAD is responsible for implementing a user interface.

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

|X| Prescription Use (Part 21 CFR 801 Subpart D) O Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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.

Date prepared: July 18th, 2023

1. **Submitter (Legal Manufacturer):**
   Siemens Healthcare GmbH
   Henkestrasse 127
   91052 Erlangen
   Germany

   Establishment Registration Number:
   3004977335

2. **Contact Person:**
   Mr. Abhineet Johri
   Regulatory Affairs Manager
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3. **Device Name and Classification:**

Trade Name:	*syngo.*CT Lung CAD (Version VD30)
Classification Name:	Medical image management and processing system
Classification Panel:	Radiology
Common Name:	Lung computed tomography system, computer-aided detection
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	OEB

4. **Legally Marketed Predicate Device:**

Trade Name:	*syngo.*CT Lung CAD (Version VD20)
510(k) Clearance:	K203258
Clearance Date:	March 31, 2021
Classification Name:	Medical image management and processing system

Classification Panel:	Radiology
Common Name:	Lung computed tomography system, computer-aided detection
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	OEB
Recall Information:	This predicate device has not been the subject of any design related recalls.

5. Device Description:

Siemens Healthcare GmbH intends to market the *syngo*.CT Lung CAD which is a medical device that is designed to perform CAD processing in thoracic CT examinations for the detection of solid pulmonary nodules (between 3.0 mm and 30.0mm) and subsolid nodules (between 5.0 mm and 30.0mm) in average diameter. The device processes images acquired with multi-detector CT scanners with 16 or more detector rows recommended.

The *syngo*.CT Lung CAD device supports the full range of nodule locations (central, peripheral) and contours (round, irregular).

The *syngo*.CT Lung CAD sends a list of nodule candidate locations to a visualization application, such as *syngo* MM Oncology, or a visualization rendering component, which generates output images series with the CAD marks superimposed on the input thoracic CT images to enable the radiologist's review. *syngo* MM Oncology (FDA clearanceK211459 and subsequent versions) is deployed on the *syngo*.via platform (FDA clearance k191040 and subsequent versions), which provides a common framework for various other applications implementing specific clinical workflows (but are not part of this clearance) to display the CAD marks. The *syngo*.CT Lung CAD device may be used either as a concurrent first reader, followed by a review of the case, or as a second reader only after the initial read is completed

The subject device and predicate device have the same basic technical characteristics. This does not introduce new types of safety or effectiveness concerns as demonstrated by the statistical analyses and additional evaluations results documented in the Statistical Analysis.

6. Intended Use:

syngo.CT Lung CAD software device is a Computer-Aided Detection (CAD) tool designed to assist radiologists in the detection of pulmonary nodules during review of multi-detector computed tomography(MDCT) examinations of the thorax (chest). The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may otherwise be overlooked.

7. Indications for Use:

syngo.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid pulmonary nodules during review of multi-detector computed tomography (MDCT) from multivendor examinations of the chest. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may be otherwise overlooked.

The syngo.CT Lung CAD device may be used as a concurrent first reader followed by a full review of the case by the radiologist, or as a second reader after the radiologist has completed his/her initial read.

The syngo.CT Lung CAD device may also be used in "solid-only" mode, where potential (or suspected) sub-solid and/or fully calcified CAD findings are filtered out.

The software device is an algorithm which does not have its own user interface component for displaying of CAD marks. The Hosting Application incorporating syngo.CT Lung CAD is responsible for implementing a user interface.

Safety and Effectiveness Information

Software design description, hazard analysis, and technical and safety information have also been completed and provided in support of this device. The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the device is of moderate level of concern, as per Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, May 2005.

The device has no PHI and is utilized only by trained professionals. The output of the device is evaluated by trained professionals as a concurrent first reader or as a second reader. Use of this device does not impact the quality or status of the original acquired data.

Substantial Equivalence:

This premarket notification assesses that while Siemens syngo.CT Lung CAD VD30 introduces changes to the cleared device (syngo.CT Lung CAD VD20, K203258) in the indications for use, the technological characteristics for of the product have remained unchanged.

Specifically, both the predicate VD20 and the subject device VD30 share the same algorithm based on Convolutional Neural Networks (CNN) and the same basic architectural workflow. However, VD30 extends the indication for use of VD20 by introducing:

I. The syngo.CT Lung CAD device may also be used in "solid-only" mode, where potential (or suspected) sub-solid and/or fully calcified CAD findings are filtered out.

This extension does not introduce new types of safety or effectiveness questions. As demonstrated by the statistical analysis and the results of the standalone benchmark evaluation:

I. The standalone accuracy has shown that the sensitivity of VD30 in solid-only mode is not inferior to VD20 in standard mode

II. The mean number of false positives per subject is significantly lower with VD30 in solid-only mode

In summary, Siemens Healthcare GmbH is of the opinion that the *syngo*.CT Lung CAD software, as described within this document, does not pose any unmitigated safety risks and is substantially equivalent to the predicate device.

8. Summary of Differences between the Subject Device and the Predicate Device:

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison Table 1 and Table 2 below.

Subject Device Characteristic	**Current Predicate Device *syngo*.CT Lung CAD (VD20) (**K203258)	**New Device *syngo*.CT Lung CAD (VD30)**	**Type of Change and Impact to Safety & Effectiveness**
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	[**Unchanged**] No Impact
Detection target	Solid and subsolid pulmonary nodules in screening and diagnostic chest CT acquisitions	Solid and subsolid pulmonary nodules in screening and diagnostic chest CT acquisitions	[**Unchanged**] No Impact
Intended Use	syngo.CT Lung CAD software device is a Computer-Aided Detection (CAD) tool designed to assist radiologists in the detection of pulmonary nodules during review of multi-detector computed tomography (MDCT) examinations of the thorax (chest). The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may otherwise be overlooked.	syngo.CT Lung CAD software device is a Computer-Aided Detection (CAD) tool designed to assist radiologists in the detection of pulmonary nodules during review of multi-detector computed tomography (MDCT) examinations of the thorax (chest). The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may otherwise be overlooked.	[**Unchanged**] No impact

Indications For Use	• The *syngo*.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid pulmonary nodules during review of multivendor, multi-detector computed tomography (MDCT) examinations of the chest. • The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may be otherwise overlooked. • The *syngo*.CT Lung CAD device is to be used either as a concurrent first reader, followed by radiologist review, or as a second reader after the radiologist has completed his/her initial read. • The software device is an algorithm which does not have its own user interface component for displaying of CAD marks. The hosting Application incorporating syngo.CT Lung CAD is responsible for implementing a user interface.	• *syngo*.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid pulmonary nodules during review of multi-detector computed tomography (MDCT) from multivendor examinations of the chest. • The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may be otherwise overlooked. • The *syngo*.CT Lung CAD device may be used as a concurrent first reader followed by a full review of the case by the radiologist or as a second reader after the radiologist has completed his/her initial read. • The syngo.CT Lung CAD device may also be used in "solid-only" mode, where potential (or suspected) sub-solid and/or fully calcified CAD findings are filtered out. • The software device is an	[**Updated**] Included a solid only mode to enable only displaying solid nodules (excluding fully calcified nodules and non-solid nodules)

		algorithm which does not have its own user interface component for displaying of CAD marks. The hosting Application incorporating syngo.CT Lung CAD is responsible for implementing a user interface.	
Nodule Characteristics	**Size** • Solid ≥ 3 mm and ≤ 30mm • Subsolid ≥ 5 mm and ≤ 30 mm **Locations** • full range: central, peripheral **Contours**: round, irregular	**Diameter** • Solid ≥ 3 mm and ≤ 30mm • Subsolid ≥ 5 mm and ≤ 30 mm **Locations** • full range: central, peripheral **Contours**: • round, irregular	[**Unchanged**] No impact
Reader Workflow	concurrent first reader OR second reader workflow	concurrent first reader OR second reader workflow	[**Unchanged**] No impact
Input scanning parameters	**Scanners** Multi-vendor and multi-detector CT (MDCT) scanners.	**Scanners** Multi-vendor and multi-detector CT (MDCT) scanners.	[**Unchanged**] No Impact
	Detector rows 16 or more detector rows recommended	**Detector rows** 16 or more detector rows recommended	[**Unchanged**] No impact
	Scan area The scan area needs to comprise the entire thorax covering the lung apices to the bases (single breath hold recommended)	**Scan area** The scan area needs to comprise the entire thorax covering the lung apices to the bases (single breath hold recommended)	[**Unchanged**] No impact
	Scan direction Cranio-caudal or caudal-cranial	**Scan direction** Cranio-caudal or caudal-cranial	[**Unchanged**] No Impact

	Voltage 100 -140 kVp	**Voltage** 100 -140 kVp	[**Unchanged**] No impact
	Collimation 1 mm or less	**Collimation** 1 mm or less	[**Unchanged**] No Impact
	Slice Thickness Up to and including 2.5 mm with 1.25 mm preferred	**Slice Thickness** Up to and including 2.5 mm with 1.25 mm preferred	[**Unchanged**] No Impact
	Slice overlap 0–50% Note: Reconstruction overlap is allowed, but gaps are not permitted	**Slice Overlap** 0–50% Note: Reconstruction overlap is allowed, but gaps are not permitted	[**Unchanged**] No impact
	Kernel Consistent with thoracic CT protocols and in line with patient safety guidelines. Kernels were grouped as to their profile. Typical kernels validated by the reader study were: Smooth: B, B30f, Standard, FC10. Medium: C, B45f, B50f, Lung, FC50, FC51, Bv49d_2, I50f_2, B60f. Sharp: D, B70f, Bone, FC52 .	**Kernel** Consistent with thoracic CT protocols and in line with patient safety guidelines. Kernels were grouped as to their profile. Typical kernels validated by the reader study were: Smooth: B, B30f, Standard, FC10. Medium: C, B45f, B50f, Lung, FC50, FC51, Bv49d_2, I50f_2, B60f. Sharp: D, B70f, Bone, FC52.	[**Unchanged**] No impact

	Dose Consistent with thoracic CT protocols and in line with patient safety guidelines. Typical values are: CTDIvol < 8.0 mGy (milligray) in diagnostic protocols and CTDIvol of = 3.0 mGy in screening protocols. These values are defined for standard sized patient—5 ft 7 in., 154 lb (170 cm, 70 kg)—based on a 32-cm reference phantom with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients.None	**Dose** Consistent with thoracic CT protocols and in line with patient safety guidelines. Typical values are: CTDIvol < 8.0 mGy (milligray) in diagnostic protocols and CTDIvol of = 3.0 mGy in screening protocols. These values are defined for standard sized patient—5 ft 7 in., 154 lb (170 cm, 70 kg)—based on a 32-cm reference phantom with appropriate reductions in CTDIvol for smaller patients and appropriate increases in CTDIvol for larger patients.None	[**Unchanged**] No impact
Hosting Platform	*syngo*.via	*syngo.via*	[**Unchanged**] No impact
Hosting Application	*syngo* MM Oncology	*syngo* MM Oncology	[**Unchanged**] No impact

Table 1 Summary of Differences between the Subject Device and the Predicate Device

Functional Component	LungCAD VD20	LungCAD VD30
Preprocessing Standardization of the input images and lung segmentation	(a) isotropic volume resampling and image standardization. (b) lung segmentation is accomplished using a CNN. Initially a coarse estimation of the lung is performed using a V-net process. Using two predefined bounding boxes left and right lungs are	(a). Isotropic volume resampling and image standardization (b) lung segmentation is accomplished by computing masks of right upper (RUL), right middle (RML), right lower (RLL), left upper (LUL), and left lower (LLL) lobes for a given CT dataset of chest. The segmentation task is designed as a voxel level classification task for predicting it as one of the lung lobe labels or the

	initialized. Another V-net is used to segment left and right lungs. This is followed by up-sampling to the original image resolution.	background label. The output is a probability map indicating how likely each voxel belongs to each lung lobe. The algorithm is trained on lung CT data including comorbidities for robustness.
Candidate Generation The partitioned volume is processed using a CNN and filtered to yield a list of candidates for each subvolume.	(a) isotropic volume is partitioned into subvolumes (b) Each subvolume is fed to a CNN to compute features ("response volume"). Filtering and non-maximum suppression yield a list of candidates for each subvolume (c) candidates above a certain threshold score are passed to the next step.	(a) isotropic volume is partitioned into subvolumes (b) Each subvolume is fed to a CNN to compute features ("response volume"). Filtering and non-maximum suppression yield a list of candidates for each subvolume (c) candidates above a certain threshold score are passed to the next step.
Candidate Classification utilizes a CNN-based classifier to process each candidate and estimate the likelihood of its type as either "nodule" or "non-nodule".	CNN is used for feature computation for each candidate. (a) The input image patch is firstly processed by batch normalization. (b) Three group blocks of operations are computed. In each block, a convolution, followed by a batch normalization and then a ReLU activation are used. Residual blocks and concatenation operations are used for robustness (c) Semantic features from image features are computed using two fully connected layers. (d) A soft-max function, applied to each candidate, assigns 2 values corresponding to the probability of being a nodule or being a false positive.	CNN is used for feature computation for each candidate. (a) The input image patch is firstly processed by batch normalization. (b) Three group blocks of operations are computed. In each block, a convolution, followed by a batch normalization and then a ReLU activation are used. Residual blocks and concatenation operations are used for robustness. (c) Semantic features from image features are computed using two fully connected layers. (d) A soft-max function, applied to each candidate, assigns 2 values corresponding to the probability of being a nodule or being a false positive. (e) A weighted-sum of the scores from this phase and the results of the prior step is computed. Candidates above a certain threshold score are labeled as nodule candidates.

	(e) A weighted-sum of the scores from this phase and the results of the prior step is computed. Candidates above a certain threshold score are labeled as nodule candidates.	
Postfiltering[1]	This step includes the application of two cascaded filters. These two filters aim at removing false positives originating from the colon and calcified protrusions (for example, areas where the sternum meets the manubrium, spine malformations, osteophytes, and so on). The first filter is a CNN-based classifier that has a similar structure to that of the classifier used in the candidate classification step. The second filter uses three orthogonal slices at the candidate location as input to three CNN-based classifiers (one per slice). The results from the three classifiers are then combined by a max-voting mechanism. Any candidate deemed a false positive by either filter is thus removed.	This step includes the application of three cascaded filters. The first one aims at removing false positives originating from the colon and the second one aims at removing false positives from calcified protrusions (for example, areas where the sternum meets the manubrium, spine malformations, and so on).The third one aims at assigning nodule type labels to all findings (solid, nonsolid, fully calcified). The first filter is a CNN-based classifier that has a similar structure to that of the classifier in step 3. The second filter uses three orthogonal slices at the candidate location as input to three CNN-based classifiers (one per slice). The results from the three classifiers is then combined by a max-voting mechanism. Any candidate deemed a false positive by either filter is thus removed. The third filter has two parts. The first part is a CNN-based classifier that has a similar structure to that of the classifier used in the candidate classification step., which classifies findings into solid and

[1] The third filter was added in VD30.

		non-solid groups. The second filter is constructed by using a set of hand-crafted rules based on features extracted from Raycast methods. The second filter further labels some of the solid nodules as "fully calcified". User could choose to display findings in "solid only" mode so that non-solid nodules and fully calcified nodules are excluded.
Final Candidate List	The location information of all the nodule candidates are collected into a final candidate list passed to the Hosting Application	The location information of all the nodule candidates are collected into a final candidate list passed to Hosting Application.

Table 2 Functional Components for syngo.CT Lung CAD VD20 (predicate) and syngo.CT Lung CAD VD30 (Subject device)

9. Statistical Analysis Summary

The standalone performance analysis was designed to demonstrate the substantial equivalence between syngo.CT Lung CAD VD30A (VD30) and the predicate device syngo.CT Lung CAD VD20. It included two parts. The first one, focused on demonstrating that

i) the sensitivity of VD30 in solid-only mode is not inferior to VD20 in standard mode.
ii) the mean number of false positives per subject is significantly lower with VD30 in solid-only mode and
iii) that the 2 CAD systems overlap in TPs and FPs;

while the second part focused on comparing the lesion-level sensitivity and mean number of FPs/subject of the 2 CAD systems, both in standard mode, for identifying any nodules and showing that the sensitivity and mean number of FPs/subject of VD30 in standard mode are not inferior to VD20 in standard mode.

The same retrospectively collected 712 CT thoracic cases, as used in the submission for the predicate device VD20 (K203258), were included in this evaluation. The data came from 3 sources: The UCLA study (232 cases), the original PMA study (145 cases) and some additional cases (335 cases). Each CT scan had been performed using a routine clinical protocol that was standard for each participating institution. The reference standard for the UCLA data was determined as part of the reader study (K203258). For the cases coming from the PMA study, ground truth was

established by 18 readers, where 9 of 18 readers are needed for declaring a finding as a true nodule. For the addition cases, ground truth was established by 7 readers, where 4 of the 7 readers are needed for declaring a finding as a true nodule. There were 929 true nodules from 412 cases. Of the 3560 lung lobes, 647 contained at least one true nodule and 2913 contained no true nodules, as determined by the reference standard.

All endpoints of the analyses were satisfactorily met.

The statistical analyses have provided the required evidence to demonstrate that the primary as well as the secondary endpoints were met; thus, demonstrating that the new device syngo.CT Lung CAD VD30 is substantially equivalent to the predicate syngo.CT Lung CAD VD20.

Hence, the new device was shown to be: (a) as safe and effective as the legally marketed predicate device and (b) not to raise questions of safety and effectiveness compared to the predicate device with respect to the extensions of the indication for use.

10. Non-clinical Performance Testing:

Non-clinical tests were conducted for the device *syngo*.CT Lung CAD (during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens Healthcare GmbH claims conformance to the following standards:

- ISO 14971:2019 Third Edition 2019-12IEC 62304 Edition 1.1 2015-06 Consolidated Version
- IEC 62366-1 Edition 1.0 2015-02

11.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. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the device *syngo*.CT Lung CAD during product development.

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 for the device was found acceptable to support the claims of substantial equivalence.

Summary:
Performance tests were conducted to test the functionality of the device *syngo*.CT Lung CAD . These tests have been performed to assess the functionality of the subject device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

12. Safety and Effectiveness Information:

Software specifications, design descriptions, hazard analysis, and labeling information are submitted in support of this premarket notification. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device.

The results of the hazard analysis combined with the appropriate preventive measures taken indicate the device is of moderate level of concern, as per the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

13. Conclusion as to Substantial Equivalence:

This premarket notification assesses that while Siemens *syngo.*CT Lung CAD VD30 introduces change to the cleared device (*syngo*.CT Lung CAD VD20) in the indication for use, the technological characteristics of the product and intended use have remained unchanged.

Specifically, both the predicate VD20 and VD30 share the same algorithm based on Convolutional Neural Networks (CNN) and the same basic architectural workflow.
The bug fixes and addition of the postfiltering do not introduce new types of safety or effectiveness questions as demonstrated in the statistical analysis.

The substantial equivalence comparison is performed with the previously cleared VD20 version of this device, as reflected in the predicate labeling and provided in the 510(k) cleared in March 2021 (K203258).

In summary, Siemens Healthcare GmbH is of the opinion that the *syngo*.CT Lung CAD software, as described within this document, does not pose any unmitigated safety risks and is substantially equivalent to the predicate device since its accuracy has been shown to be superior to the predicate device and the marks are reasonably consistent.