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

March 31, 2021

Re: K203258
Trade/Device Name: syngo.CT Lung CAD (VD20)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: OEB
Dated: February 19, 2021
Received: February 22, 2021

Dear Mr. Abhineet:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203258

Device Name
syngo.CT Lung CAD (VD20)

Indications for Use *(Describe)*

The syngo.CT Lung CAD device is a Computer-Aided Detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid (part-solid and ground glass) 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 otherwise be 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 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)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

K203258

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: November 04, 2020

1. **Submitter (Legal Manufacturer):**

Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany

Establishment Registration Number:
3004977335

2. **Contact Person:**

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3. **Device Name and Classification:**

Trade Name:	*syngo.*CT Lung CAD (Version VD20)
Classification Name:	Lung computed tomography system, computer-aided detection
Classification Panel:	Radiology
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 VC30)

510(k) Clearance:	K193216
Clearance Date:	March 2020
Classification Name:	Lung computed tomography system, computer-aided detection
Classification Panel:	Radiology
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 (part-solid and ground glass) 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.

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 clearance k191309) is deployed on the *syngo*.via platform (FDA clearance k191040), 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 results of the reader study 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 examinations of the 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:

The syngo.CT Lung CAD device is a Computer-Aided Detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid (part-solid and ground glass) 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 otherwise be 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 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 VD20 introduces changes to the cleared device (*syngo*.CT Lung CAD VC30) in the indications for use and extends the workflow to concurrent first reader, the technological characteristics of the product and intended use have remained unchanged.

Specifically, both the predicate VC30 and VD20 share the same algorithm based on Convolutional Neural Networks (CNN) and the same basic architectural workflow. However, VD20C extends the indication for use of VC30 by introducing:

(1) new AI models for Candidate Generation and Classification components to support the extension of the claims.
(2) regional configurability of the workflow so that the device, subject to configuration controls, may be also used for outside the US Market.
(3) a post-filtering module (also CNN-based) aimed at reducing false positives caused by bony protrusions or detections in the colon.
(4) bug-fixes to address apical or basal-lungs under-segmentation.

These extensions do not introduce new types of safety or effectiveness questions. As demonstrated by (a) the statistical analysis following the MRMC reader study and results of the standalone Mark Overlap evaluations. Specifically:

i. The results from the analysis of the retrospective reader study meet the end points and as such validate that the new device VD20 (point 1 above) is safe and effective
ii. Regional configurability does not impact the safety and effectiveness of the device as the configurability does not affect the workflow nor the operational aspects of the device.
iii. The reduction of false positives by post-filtering (point 3 above) and bug-fixes (point 4 above) are subjects of the standalone analysis which has demonstrated that the marks generated by the two devices are reasonably consistent.

Note: The substantial equivalence comparison is performed with the previously cleared VC30 version of this device, as reflected in the predicate labeling and provided in the 510(k) cleared in March 2020 (K193216).

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 (VC30) (K193216)**	**New Device *syngo*.CT Lung CAD (VD20)**	**Type of Change and Impact to Safety & Effectiveness**
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	[**Unchanged**] No Impact
Detection target	Solid pulmonary nodules in diagnostic chest CT acquisitions	Solid and subsolid (part-solid and ground-glass) pulmonary nodules in screening and diagnostic chest CT acquisitions	[**Updated**] Reflecting parameters validated in the reader study.
Intended Use	The LungCAD software device is a Computer-Aided Detection (CAD) tool designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector computed tomographic (MDCT) thoracic examinations. The software is an adjunctive tool that alerts the radiologist to regions of interest (ROI) that may be initially overlooked. The LungCAD software device use is intended to be used as a second reader after the radiologist has completed his/her initial read.	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) thoracic examinations. The software is an adjunctive tool to alert the radiologist to regions of interest (ROI) that may otherwise be overlooked.	[**Updated**] Reflecting key aspects for the intended use. Details that explicitly relate to the indication for use have been removed and are included in the indications for use (see below).

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 pulmonary nodules during review of 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 have been initially overlooked. • The *syngo*.CT Lung CAD device is intended to be used as a second reader after the radiologist has completed his/her initial read.	• The *syngo*.CT Lung CAD device is a computer-aided detection (CAD) tool designed to assist radiologists in the detection of solid and subsolid (part-solid and ground glass) 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 maybe 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 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.	[**Updated**] Reflecting parameters validated in the reader study. Extensions include: - subsolid (part-solid and ground glass) nodules - multivendor (Siemens, Ge, Philips, and Toshiba - concurrent first reader workflow - clarification on the fact that the device does not have its own user interface

Nodule Characteristics	**Size** • Solid ≥ 3mm and ≤ 20mm **Locations** • full range: central, peripheral **Contours**: • round, irregular	**Diameter** • Solid ≥ 3mm and ≤ 30mm • Subsolid (part-solid and ground glass) ≥ 5mm and ≤ 30mm **Locations** • full range: central, peripheral **Contours**: • round, irregular	[**Extended**] - Solid nodules to 30mm - Included Subsolid (part-solid and ground glass) nodules - Validated by reader study
Reader Workflow	second reader workflow	concurrent first reader OR second reader workflow	[**Updated**] Reflecting parameters validated in the reader study.
Input scanning parameters	**Scanners** Siemens multi-detector CT (MDCT) scanners.	**Scanners** Multi-vendor and multi-detector CT (MDCT) scanners (Siemens, GE, Philips, and Toshiba)	[**Updated**] Reflecting parameters validated in the reader study.
	Detector rows 4 or more detector rows	**Detector rows** 16 or more detector rows	[**Updated**] Recommendation to use 16 or more detector rows included, as recommended by FDA, Reflecting parameters validated in the reader study.
	Scan area The scan area needs to comprise the entire thorax covering the lung apices to the bases	**Scan area** The scan area needs to comprise the entire thorax covering the lung apices to the bases (single breath hold recommended)	[**Updated**] Clarification added; no Impact
	Scan direction Cranio-caudal or caudal-cranial	**Scan direction** Cranio-caudal or caudal-cranial	[**Unchanged**] No Impact

	Voltage 120 -140 kVp	**Voltage** 100 -140 kVp	[**Updated**] Reflecting parameters validated in the reader study.
	Exposure 40–120 mAs	None	[**Removed**] Aspect captured by the Dose recommendation
	Collimation 1 mm or less	**Collimation** 1 mm or less	[**Unchanged**] No Impact
	Slice width 1.00 - 1.25 mm	**Slice Thickness** Up to and including 2.5mm, it is recommended that <= 1.25 mm be used for the detection of smaller nodules (e.g. 3.0mm)	[**Updated**] Reflecting parameters validated in the reader study.
	Slice overlap 0–25% Note: Reconstruction overlap is allowed, but gaps are not permitted	**Slice Overlap** 0–50% Note: Reconstruction overlap is allowed, but gaps are not permitted	[**Updated**] Reflecting parameters validated in the reader study.
	Number of images Up to 1000 images per series.	None	[**Removed**] No longer a technological limitation
	Kernel Siemens B60	**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 .	[**Updated**] Reflecting parameters validated in the reader study.

	Contrast Intravenous contrast enhancement is optional	None	[**Removed**] Insufficient data in the reader study to substantiate this characteristic.
	Dose Diagnostic	**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.	**[Extended]** Dose characteristic has been updated, as discussed with FDA, to reflect the data for diagnostic and screening protocols included and validated as part of the reader study.
Hosting Platform	*syngo*.via (VB50)	*syngo*.via (VB60)	**[Unchanged]** and no Impact
Hosting Application	*syngo* MM Oncology	*syngo* MM Oncology	**[Unchanged]** and no Impact

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

Functional Component	LungCAD VC30	LungCAD VD20
Preprocessing Standardization of the input images and lung segmentation	(a) isotropic volume resampling (b) lung segmentation is accomplished using a CCN. Initially a coarse estimation of the lung is performed using a V-net process. Using two predefined bounding boxes left and right lungs are initialized. Another V-net is used to segment left and right lungs. This is followed by up-sampling to the original image resolution.	(a) isotropic volume resampling (b) lung segmentation is accomplished using a CCN. Initially a coarse estimation of the lung is performed using a V-net process. Using two predefined bounding boxes left and right lungs are initialized. Another V-net is used to segment left and right lungs. This is followed by up-sampling to the original image resolution.
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 blocks of operations are computed. In each block, a convolution, with stride 2, is used for down-sampling instead of max-pooling. (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.	CNN is used for feature computation for each candidate. (a) The input image patch is firstly processed by batch normalization. (b) Three blocks of operations are computed. In each block, a convolution, with stride 2, is used for down-sampling instead of max-pooling. (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.

Postfiltering[1]		Postfiltering This step includes the application of two cascaded filters. The first one aims at removing false positives originating (a) from the colon and a second one from (b) calcified protrusions (for example, areas where the sternum meets the manubrium, spine malformations, and osteophytes, and so on). 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 CCN-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
Final Candidate List	The location information of all the nodule candidates are collecte 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 VC30 (predicate) and syngo.CT Lung CAD VD20 (Subject device)

[1] This component was added in version d into VD20C (September 2020). It has been validated as part of the VD20+ paired overlap analysis.

9. Statistical Analysis Summary

The statistical analyses aimed at substantiating the safety and effectiveness of LungCAD VD20. The aim of the pivotal study was that of assessing the effect on readers' diagnostic accuracy when using Lung CAD, relative to their unaided accuracy.

20 readers reviewed all of 232 cases using both a second-reader as well as a concurrent first reader workflows. Following the read according to both workflows, five expert radiologists reviewed all consolidated marks. The reference standard was based on reader majority (three out of five) followed by expert adjudication, as needed. As a result of the study's truthing process, 143 cases were identified as including at least one true nodule and 89 with no true nodules.

All endpoints of the analyses were satisfactorily met. These analyses demonstrated that all readers showed a significant improvement for the detection of pulmonary nodules (solid, part-solid and ground glass) with both reading workflows.

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 VD20 is substantially equivalent to the predicate syngo.CT Lung CAD VC30.

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 performance testing was performed at various levels for verification and validation of the device intended use and to ensure safety and effectiveness.

The protocol of the tests follows the testing activities of the software development and quality management process. This protocol, which ensures both verification and validation, is structured at different levels of product testing to ensure that the above objectives are met. These are:

- Unit test: Verify the Design Specification, Risk Mitigations, identify runtime errors and memory leaks, and Verify the Logic.
- Integration test: Verify the correct implementation of the design and test coverage specified by the software requirements and Design Specifications. The

Implementation and effectiveness of Risk mitigation classified as Hazard is also checked (Hazard Tests).

- System test: It is performed on the integrated product comprising the software units and components.
- System Validation: Validate the intended use defined in the requirements specifications and risk labelling mitigations. These requirements will be validated using one of the Hosting Applications.

Tests specifications used for the test levels mentioned above include test descriptions, test environment, and the test cases with the requirements that were tested. Tests are passed only based on the defined acceptance criteria. To ensure continuous quality of the software, automatic testing with GUI- (graphical user interface) and Non-GUI-based tests are performed to cover the software's functionality. The basis for the test automation is described in the corresponding Test Specifications. The matching of automated test cases and test results is ensured through code reviews of the automation scripts.

Siemens Healthcare GmbH claims conformance to the following standards:

- ISO 14971:2007Second edition 2007-03-01
- IEC 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 VD20 introduces change to the cleared device (*syngo*.CT Lung CAD VC30) in the indication for use and extends the workflow to concurrent first reader, the technological characteristics of the product and intended use have remained unchanged.

Specifically, both the predicate VC30 and VD20 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 following the MRMC reader study and results of the standalone Mark Overlap evaluations.

The substantial equivalence comparison is performed with the previously cleared VC30 version of this device, as reflected in the predicate labeling and provided in the 510(k) cleared in March 2020 (K193216).

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.