February 24, 2023

Coreline Soft Co.,Ltd.
℅ Hyeyi Park
RA Manager
4,5F(Yeonnam-dong), 49, World Cup buk-ro 6-gil, Mapo-gu
Seoul, 03991
SOUTH KOREA

Re: K221592
Trade/Device Name: AVIEW Lung Nodule CAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: OEB, LLZ
Dated: January 25, 2023
Received: January 26, 2023

Dear Hyeyi Park:

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 Imaging Devices
and Electronic Products
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)*
K221592

Device Name
AVIEW Lung Nodule CAD

Indications for Use *(Describe)*
AVIEW Lung Nodule CAD is a Computer-Aided Detection (CAD) software designed to assist radiologists in the detection of pulmonary nodules (with diameter 3-20 mm) during the review of CT examinations of the chest for asymptomatic populations. AVIEW Lung Nodule CAD provides adjunctive information to alert the radiologists to regions of interest with suspected lung nodules that may otherwise be overlooked. AVIEW Lung Nodule CAD may be used as a second reader after the radiologist has completed their initial read. The algorithm has been validated using non-contrast CT images, the majority of which were acquired on Siemens SOMATOM CT series scanners; therefore, limiting device use to use with Siemens SOMATOM CT series is recommended.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K221592

1 SUBMITTER

Coreline Soft Co., Ltd.
4,5F (Yeonnam-dong), 49 World Cup buk-ro 6-gil, Mapo-gu, Seoul, 03991, Republic of Korea.

Phone: 82.2.517.7321
Fax: 82.2.571.7324

Contact Person: Hyeyi. Park
Date Prepared: 05.31.2022

2 DEVICE

Name of Device: AVIEW Lung Nodule CAD
Classification Name: Medical Image Management and Processing System.
Classification Panel: Radiology
CFR Section: (21CFR 892.2050)
Regulatory Class: II
Product Code: OEB, LLZ

3 PREDICATE DEVICE

Syngo.CT Lung CAD(VD20) by Siemens Healthcare GmbH (K203258)
Name of Device: syngo. CT Lung CAD (VD20)
Classification Name: Medical Image Management and Processing System.
Classification Panel: Radiology
CFR Section: (21CFR 892.2050)
Regulatory Class: II
Product Code: OEB

This predicate has not been subject to a design-related recall.

4 REFERENCE DEVICE

InferRead Lung CT.AI by Beijing Infervision Technology Co., Ltd. (K192880)
Name of Device: InferRead Lung CT.AI
Classification Name: Medical Image Management and Processing System
Classification Panel: Radiology
CFR Section: (21CFR 892.2050)
Regulatory Class: II

Product Code: OEB, LLZ

AVIEW by Coreline Soft Co., Ltd. (K200714)

Name of Device: AVIEW
Classification Name: Medical Image Management and Processing System
Classification Panel: Radiology
CFR Section: (21CFR 892.2050)
Regulatory Class: II
Product Code: LLZ, JAK

All reference devices have not been subject to a design-related recall.

5 DEVICE DESCRIPTION

The AVIEW Lung Nodule CAD is a software product that detects nodules in the lung. The lung nodule detection model was trained by Deep Convolution Neural Network (CNN) based algorithm from the chest CT image. Automatic detection of lung nodules of 3 to 20mm in chest CT images. By complying with DICOM standards, this product can be linked with the Picture Archiving and Communication System (PACS) and provides a separate user interface to provide functions such as analyzing, identifying, storing, and transmitting quantified values related to lung nodules. The CAD's results could be displayed after the user's first read, and the user could select or de-select the mark provided by the CAD. The device's performance was validated with SIEMENS' SOMATOM series manufacturing. The device is intended to be used with a cleared AVIEW platform.

6 INDICATIONS FOR USE

AVIEW Lung Nodule CAD is a Computer-Aided Detection (CAD) software designed to assist radiologists in the detection of pulmonary nodules (with diameter 3-20 mm) during the review of CT examinations of the chest for asymptomatic populations. AVIEW Lung Nodule CAD provides adjunctive information to alert the radiologists to regions of interest with suspected lung nodules that may otherwise be overlooked. AVIEW Lung Nodule CAD may be used as a second reader after the radiologist has completed their initial read. The algorithm has been validated using non-contrast CT images, the majority of which were acquired on Siemens SOMATOM CT series scanners; therefore, limiting device use to use with Siemens SOMATOM CT series is recommended.

7 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

AVIEW Lung Nodule CAD has the same intended use and the principle of operation and has similar features to the predicate devices. Snygo.CT Lung CAD (VD20) (K203258). There might be slight differences in features and menu, but these differences between the predicate device and the proposed device are not so significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation and verification tests, we conclude that the proposed device is substantially equivalent to the predicate devices.

Characteristic	Subject Device	Predicate Device	Reference Device	Reference Device
Device Name	**AVIEW Lung Nodule CAD**	**syngo. CT Lung CAD (VD20)**	**InferRead Lung CT.AI**	**AVIEW**
Classification Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Medical Image Management and Processing System	Medical Image Management and Processing System
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	OEB, LLZ	OEB	OEB, LLZ	LLZ, JAK
Review Panel	Radiology	Radiology	Radiology	Radiology
510k Number	K221592	K203258	K192880	K200714
Indications for use	**AVIEW Lung Nodule CAD** AVIEW Lung Nodule CAD is a Computer-Aided Detection (CAD) software designed to assist radiologists in the detection of pulmonary nodules (with diameter 3-20 mm) during the review of CT examinations of the chest for asymptomatic populations. AVIEW Lung Nodule CAD provides adjunctive information to alert the radiologists to regions of interest with suspected lung nodules that may otherwise be overlooked. AVIEW Lung Nodule CAD may be used as a second reader after the radiologist has completed their initial read. The algorithm has been validated using non-contrast CT images, the majority of which were acquired on Siemens SOMATOM CT series scanners; therefore, limiting device use to use with Siemens SOMATOM CT series is recommended. **syngo. CT Lung CAD (VD20)** 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. **InferRead Lung CT.AI** lnferRead Lung CT.AI is comprised of computer-assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during the review of CT examinations of the chest on an asymptomatic population. Infer Read Lung CT.AI requires that both lungs be in the field of view. lnferRead Lung CT.AI provides adjunctive information and is not intended to be used without the original CT series. **AVIEW** AVIEW provides CT values for pulmonary tissue from CT thoracic and cardiac datasets. This software could be used to support the physician quantitatively in the diagnosis, follow up evaluation and documentation of CT lung tissue images by providing image segmentation of sub-structures in lung, lobe, airways and cardiac, registration of inspiration and expiration which could analyze quantitative information such as air trapping volume, air trapped index, and inspiration/expiration ratio. And, volumetric and structure analysis, density evaluation and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data set on premise and as cloud environment as well to allow users to connect by various environment such as mobile devices and chrome browser. Characterizing nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include nodule type, location of the nodule			

	and measurements such as size (major axis, minor axis), estimated effective diameter from the volume of the nodule, volume of the nodule, Mean HU(the average value of the CT pixel inside the nodule in HU), Minimum HU, Max HU, mass(mass calculated from the CT pixel value), and volumetric measures(Solid major; length of the longest diameter measured in 3D for solid portion of the nodule, Solid 2nd Major: The length of the longest diameter of the solid part, measured in sections perpendicular to the Major axis of the solid portion of the nodule), VDT (Volume doubling time), and Lung-RADS (classification proposed to aid with findings). The system automatically performs the measurement, allowing lung nodules and measurements to be displayed and, integrate with FDA certified Mevis CAD (Computer aided detection) (K043617). It also provides CAC analysis by segmentation of four main artery (right coronary artery, left main coronary, left anterior descending and left circumflex artery then extracts calcium on coronary artery to provide Agatston score, volume score and mass score by whole and each segmented artery type. Based on the score, provides CAC risk based on age and gender.
General Description	**AVIEW Lung Nodule CAD**
	The AVIEW Lung Nodule CAD is a software product that detects nodules in the lung. The lung nodule detection model was trained by Deep Convolution Neural Network (CNN) based algorithm from the chest CT image. Automatic detection of lung nodules of 3 to 20mm in chest CT images. By complying with DICOM standards, this product can be linked with the Picture Archiving and Communication System (PACS) and provides a separate user interface to provide functions such as analyzing, identifying, storing, and transmitting quantified values related to lung nodules. The CAD's results could be displayed after the user's first read, and the user could select or de-select the mark provided by the CAD. The device's performance was validated with SIEMENS' SOMATOM series manufacturing. The device is intended to be used with a cleared AVIEW platform.
	syngo. CT Lung CAD (VD20)
	Simens 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 5.0mm and 30.0mm) in average diameter. The device processes image 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, pe-ripheral) 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.
	InferRead Lung CT.AI
	InferRead Lung CT.AI uses the Browser/Server architecture and is provided as Software as a Service (SaaS) via a URL. The system integrates algorithm logic and database in the same server to ensure the simplicity of the system and the convenience of system maintenance. The server is able to accept chest CT images from a PACS system, Radiological Information System (RIS system) or directly from a CT scanner, analyze the images and provide output annotations regarding lung nodules. Users are then able to use an existing PACS system to view the annotations

	on their workstations. Dedicated servers can be located at hospitals and are directly. connected to the hospital networks. The software consists of 4 modules which are Image reception (Docking Toolbox), Image predictive processing (DLServer), Image storage (RePACS) and Image display (NeoViewer).			
	AVIEW			
	The AVIEW is a software product which can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0 which is the digital image and communication standard in medicine. It also offers functions such as reading, manipulation, analyzing, post-processing, saving, and sending images by using the software tools. And is intended for use as diagnostic patient imaging which is intended for the review and analysis of CT scanning. Provides following features as semi-automatic nodule management, maximal plane measure, 3D measures and columetric measures, automatic nodule detection by integration with 3rd party CAD. Also provides Brocks model which calculated the malignancy score based on numerical or Boolean inputs. Follow up support with automated nodule matching and automatically categorize Lung-RADS score which is a quality assurance tool designed to standardize lung cancer screening CT reporting and management recommendations that is based on type, size, size change and other findings that is reported. It also automatically analyzes coronary artery calcification which support user to detect cardiovascular disease in early stage and reduce the burden of medical.			
Detection target(s)	pulmonary nodules in non-contrast chest CT acquisitions	Solid and subsolid (part-solid and ground-glass) pulmonary nodules in screening and diagnostic chest CT acquisitions.	solid pulmonary nodules in diagnostic chest CT acquistions	-
Nodule Characteristics	**Diameter:** · Pulmanoary nodules ≥ 3 mm and <20 mm **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	Solid nodules ≥ 3mm and 10mm and full rande, central, peripheral round. irregular	-
Image format	DICOM	DICOM	DICOM	DICOM
Hosting Platform	AVIEW	syngo.via	-	-
Hosting Application	AVIEW LCS	Syngo MM Oncology	-	-

Outputs	DICOM GSPS (Grayscale Softcopy Presentation State) XML (Coordinate of detected nodules) Able to view results on AVIEW, AVIEW LCS viewer page	Generates output images series with the CAD makrs superimposed. Able to view results syngo MM Oncology viewer page.	-	-
Type of Scans	CT	CT	CT	CT
Input scanning parameters	**Scanners** Siemens SOMATOM CT Scanners	**Scanners** Multi-vendor and multi-detector CT (MDCT) scanners (Siemens, GE, Philips, and Toshiba)	-	-
	Detector rows 16 or more detector rows	**Detector rows** 16 or more detector rows		
	Voltage 100~140 kVp	**Voltage** 100~140 kVp		
	Exposure None	**Exposure** None		
	Collimation 1mm or less	**Collimation** 1mm or less		
	Slice Thickness Up to and including 2.5mm, it is recommended that <=1.25mm be used for the detection of smaller nodules (e.g., 4.0mm)	**Slice Thickness** Up to and including 2.5mm, it is recommended that <=1.25mm be used for the detection of smaller nodules (e.g., 3.0mm)		
	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		
	Number of images None	**Number of images** None		

	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, Br49d, B50f, I50f, Br60f, Lung, FC50, FC51 Sharp: D, B70f, I70f, B80s, I80s, Bone	**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		
	Contrast None	**Contrast** 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.	**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.		

8 PERFORMANCE DATA

8.1 Clinical performance evaluation

A HIPAA-compliant multi-case, multi-reader, retrospective study design was utilized. An image viewer without or with AI algorithms, AVIEW Lung Nodule CAD program, for lung nodule detection and measurement were used for chest CT reads. Three dedicated chest radiologists with at least ten years of experience determined the ground truth using a dataset of 151 Chest CTs with 103 negative controls and 48 cases with one or more lung nodules. All lung nodules were segmented in 3D. In a blinded fashion, eleven board-certified radiologists interpreted the same cases unassisted, followed by AI assistance after randomization and a 4-week washout period. Data were analyzed in a random reader, random case context, and one-sided tests at the 5% significance level, and 95% confidence intervals were constructed for all estimates. Reading time analyses were performed with mixed-effect Gaussian regression with a fixed effect for AI assistance and with clustering at the reader level. Post estimation marginal estimates were calculated for unassisted versus assisted read times.
The multi-reader multi-case demonstrated that aided radiologist performance for lung nodule detection was improved with statistical significance compared to unaided. Reading time was decreased when AVIEW Lung Nodule CAD aided radiologists. Also, both incidental and screening populations was included on the test dataset. We have performed subgroup analyses for several key subgroups to demonstrate generalizability. This includes assessment of performance for challenging and/or confounding cases.

- Performance Testing Results
  1. Overall unaided/aider reader performacne comparison

	Unaided	Aided	Difference in point estimate
AUC	0.73 (0.66 – 0.79)	0.92 (0.89 – 0.95)	0.19
Sensitivity	0.68 (0.62 – 0.73)	0.91 (0.89 – 0.94)	0.23
FP/scan	0.48 (0.28 – 0.69)	0.28 (0.15 – 0.42)	0.24

8.1.1 Test Report

- Clinical Study Report for AVIEW Lung Nodule CAD

8.2 Software Verification and Validation

Verification, validation, and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

8.2.1 System Test

In accordance with the document ‘integration Test Cases’ discussed in advance by the software development team and test team, the test is conducted by installing software to hardware with recommended system specifications. Despite the Test case recognized in advance was not in existence. New software error discovered by the ‘Exploratory Test’ conducted by the test team will be registered and managed as a new test case after discussion between the development team and test team.
Discovered software errors will be classified into 3 categories as severity and managed.

- ✓ Major defects are impacting the product’s intended use and no workaround is available.

- ✓ Moderate defects, which are typically related to user interface or general quality of product, while workaround is available.
- ✓ Minor defects, which are not impacting the product's intended use. Not significant.

Success standard of System Test is not finding 'Major', 'Moderate' defect.

8.2.2 Performance Test

- DICOM Test Report
- Performance Test Report
- DICOM Conformance Statement
- Thin Cient Server Compatibility Test Report
- AVIEW Lung Nodule CAD Integration Test Report
- Standalone study for AVIEW Lung Nodule CAD
  - ➢ The standalone study of AI-based lung nodule detection software compared to ground truth was evaluated with sensitivity, specificity, ROC, and FROC. We consider that the software performs successfully when the sensitivity for lung nodule detection performance at the patient level and nodule level exceeds 0.8 and the specificity exceeds 0.6, the ROC AUC for lung nodule detection performance exceeds 0.8 and the sensitivity for lung nodule detection performance exceeds 0.8 in false positive (FP)/scan < 2. Dataset are collected from three geographically distinct US clinical sites. The total number of data is 282 (140 cases with nodule data and 142 cases without nodule data). All datasets were built with images of U.S, and by gender, there were 132 males and 150 females. We validated this test by purchasing anonymized medical data. So, any data used for AI training or internal validation was not used for this test. Also, both incidental and screening populations was included on the test dataset. We have performed subgroup analyses for several key subgroups to demonstrate generalizability. This includes assessment of performance for challenging and/or confounding cases.
    - ✧ Performance Testing Results
      1. Overall AUC (with CI): 0.961(0.939-0.983)
      2. Overall Sensitivity (with CI): 0.907(0.846-0.95)
      3. Overall Specificity (with CI): 0.704(0.622-0.778)
      4. Overall sensitivity (with CI) at FP/scan<2: 0.889(0.849-0.93) at FP/scan=0.504

9 CONCLUSIONS

The new device and predicate device are substantially equivalent in the areas of technical characteristics, general functions, application, and intended use. The new device does not introduce a fundamentally new scientific technology, and the clinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the AVIEW Lung Nodule CAD described in this submission is substantially equivalent to the predicate device.