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

Re: K214036 Dec. 23, 2022
Trade/Device Name: AVIEW
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, JAK
Dated: November 25, 2022
Received: November 28, 2022

Dear Hye Yi 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,

Wenbo Li for Jessica Lamb

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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)*

K214036

Device Name

AVIEW

Indications for Use *(Describe)*

AVIEW provides CT values for pulmonary tissue from CT thoracic and cardiac datasets. This software can be used to support the physician providing quantitative analysis of CT images by image segmentation of sub-structures in the lung, lobe, airways, fissures completeness, cardiac, density evaluation, and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data set on-premises and as a cloud environment to allow users to connect by various environments such as mobile devices and Chrome browsers. Converts the sharp kernel to soft kernel for quantitative analysis of segmenting low attenuation areas of the lung. 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, the 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 measure in 3D for a solid portion of the nodule, Solid 2nd Major: The size 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 the Agatston score, volume score, and mass score by the whole and each artery by segmenting four main arteries (right coronary artery, left main coronary, left anterior descending, and left circumflex artery). Based on the calcium score provides CAC risk based on age and gender. The device is indicated for adult patients only.

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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510(k) Summary

K214036

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
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Contact Person: hyeyi. Park
Date Prepared: 12.21.2022

2 DEVICE

Name of Device: AVIEW
Common or Usual Name: Image Processing Software
Classification Name: System, image processing, radiological (21CFR 892.2050)
Regulatory Class: II
Product Code: QIH, JAK

3 PREDICATE DEVICE

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

Name of Device: AVIEW
Common or Usual Name: Image Processing Software
Classification Name: System, image processing, radiological (21CFR 892.2050)
Regulatory Class: II
Product Code: LLZ, JAK

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

4 REFERENCE DEVICE

ClariCT.AI by ClariPI Inc.(K183460)

Name of Device: ClariCT.AI
Common or Usual Name: Image Processing Software
Classification Name: System, image processing, radiological (21CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

Broncholab by Fluidda Inc.(K191550)

Name of Device: Broncholab
Common or Usual Name: Image Processing Software
Classification Name: System, X-Ray, Tomography, Computed (21CFR 892.1750)
Regulatory Class: II
Product Code: JAK

This reference device has not been subject to a design-related recall

5 DEVICE DESCRIPTION

The AVIEW is a software product that can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0, 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 software tools. And is intended for use as a quantitative analysis of CT scanning. It provides the following features such as segmentation of lung, lobe, airway, fissure completeness, semi-automatic nodule management, maximal plane measure, 3D measures and volumetric measures, automatic nodule detection by integration with 3rd party CAD. It also provides the Brocks model, which calculates 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 are based on type, size, size change, and other findings that are reported. It also provides a calcium score by automatically analyzing coronary arteries from the segmented arteries

6 INDICATIONS FOR USE

AVIEW provides CT values for pulmonary tissue from CT thoracic and cardiac datasets. This software can be used to support the physician providing quantitative analysis of CT images by image segmentation of sub-structures in the lung, lobe, airways, fissures completeness, cardiac, density evaluation, and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data set on-premises and as a cloud environment to allow users to connect by various environments such as mobile devices and Chrome browsers. Converts the sharp kernel to soft kernel for quantitative analysis of segmenting low attenuation areas of the lung. 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, the 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 measure in 3D for a solid portion of the nodule, Solid 2nd Major: The size 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 the Agatston score, volume score, and mass score by the whole and each artery by segmenting four main arteries (right coronary artery, left main coronary, left anterior descending, and left circumflex artery). Based on the calcium score provides CAC risk based on age and gender. The device is indicated for adult patients only.

7 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE

AVIEW has the same intended use and the principle of operation and has similar features to the predicate devices. AVIEW (K200714)

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**	**AVIEW**	**ClariCT.AI**	**Broncholab**
Classification Name	System, image Processing Radiological	System, image Processing Radiological	System, image Processing Radiological	System, X-Ray, Tomography, Computed
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1750
Product Code	QIH, JAK	LLZ, JAK	LLZ	JAK
Review Panel	Radiology	Radiology	Radiology	Radiology
510k Number	-	K200714	K183460	K191550
Indications for use	**AVIEW**			
	AVIEW provides CT values for pulmonary tissue from CT thoracic and cardiac datasets. This software can be used to support the physician providing quantitative analysis of CT images by image segmentation of sub-structures in the lung, lobe, airways, fissures completeness, cardiac, density evaluation, and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data set on-premises and as a cloud environment to allow users to connect by various environments such as mobile devices and Chrome browsers. Converts the sharp kernel to soft kernel for quantitative analysis of segmenting low attenuation areas of the lung. 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, the 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 measure in 3D for a solid portion of the nodule, Solid 2nd Major: The size 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 the Agatston score, volume score, and mass score by the whole and each artery by segmenting four main arteries (right coronary artery, left main coronary, left anterior descending, and left circumflex artery). Based on the calcium score provides CAC risk based on age and gender. The device is indicated for adult patients only.			
	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.
	ClariCT.AI
	ClariCT.AI, is a software device intended for networking, communication, processing, and enhancement of CT images in DICOM format regardless of the manufacturer of CT scanner or model.
	Broncholab
	Broncholab provides physicians with reproducible CT values for pulmonary tissue for providing quantitative support for diagnosis and follow-up examination. Broncholab can be used to support physicians in the diagnosis and documentation of pulmonary tissues images (e.g., abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of subcompartments, volumetric analysis, density evaluations, low density cluster analysis, fissure evaluation and reporting tools are combined with a dedicated workflow.
General Description	**AVIEW**
	The AVIEW is a software product that can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0, 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 software tools. And is intended for use as a quantitative analysis of CT scanning. It provides the following features such as segmentation of lung, lobe, airway, fissure completeness, semi-automatic nodule management, maximal plane measure, 3D measures and volumetric measures, automatic nodule detection by integration with 3rd party CAD. It also provides the Brocks model, which calculates 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 are based on type, size, size change, and other findings that are reported. It also provides a calcium score by automatically analyzing coronary arteries from the segmented arteries.
	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.
	ClariCT.AI
	ClariCT.AI software is intended for denoise processing and enhancement of CT DICOM images when higher image quality and/or lower dose acquisitions are desired. ClariCT.AI software can be used to reduce noises in CT images of the head, chest, and abdomen, in particular in CT images with a lower radiation dose. ClariCT.AI may also improve the image quality of low dose nonpdiagnostic Filtered Back Projection images as well as lterative Reconstruction images. The system enables the receipt of DICOM images from CT imaging devices (modalities), enables their denoise processing and enhancement, and transmission to a PACS workstation.
	Broncholab
	Broncholab is a SaMD (Software as Medical Device) which provides quantitative CT values that are intended to support the physician in the diagnosis and documentation of pulmonary tissues images (abnormalities) from CT scans. The CT scan images are transformed into 3D models of the patient-specific lungs using several image processing steps. Broncholab can be used to assess the effectiveness of therapy based on CT scan data. It is used along with the following accessories: ・ Web Portal: Enables the uploading of CT scans and patient data ・ Client Report: Enables the conversion of the output of Broncholab (CT values) into a desired digital format (PDF Report) and transfers this Report to the physician via email. Inspiratory CT scan images uploaded by the users are converted into quantitative CT values using a combination of software tools. Quality checks (both manual and automated) are implemented to assure the quality of the final data. The outputs are provided as absolute values and as a percentage of the total airway volume/ lung volume/ lobar volume depending on the parameter. The device can be used on a computer with a web browser installed and consists of two accessories: ・ An online portal to upload the CT scans ・ An accessory that enables the creation of the Report The CT values include: 1) Lung and Lobar Volume is the volume of the 3D model of each lung lobe. 2) Airway Volume is defined as the region from the trachea until the segmental bronchi. 3) Lung Density Scores/ Volumes is defined as all the intrapulmonary voxels with Hounsfield Units between -1024 and -950 using the inspiratory scans: • Low attenuation areas below -950 HU (LAA-950HU) • 15th percentile of density histogram: Percentile density (PD) can also be used to express Emphysema. • Blood vessel density: Blood vessel density can be determined through segmentation and 3-D reconstruction of the blood vessels. The segmentation is based on local

	geometry features and HU thresholds and is performed on the inspiratory CT scan. 4) Fissure Analysis (fissure integrity) is the percentage of completeness of the fissure. Lung fissures are a doublefold of visceral pleura that either completely or incompletely separates the lungs into lung lobes. CT scan images must be DICOM 3.0 compliant.			
Platform	IBM-compatible PC or PC network	same		
User Interface	Monitor, Mouse, Keyboard	same		
Image Input Sources	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	same		
Image format	DICOM	same		
Image Measurement Tools	Ruler (line and 3D), Tapeline (curve, poly and3D), Angle (3-point, 4point, and 3D), pixel values, area of ROI (rectangle, circle, ellipse), volume	same		
Image viewing	Axial, sagittal, and coronal image, oblique slice, cube view	same		
Image manipulation	Panning, rotating, zooming, windowing, inverting, Coloring, Oblique, Note (text overlay), Coloring	same		
DICOM	This receives DICOM data from CT by DICOM communication Conducts DICOM data communication with PACS. It also imports DICOM file directly, saves by using export function.	same		
Lung Analysis Functions	Fully automatic lungs, lobes and airways segmentation using deep-learning algorithms	Fully automatic lungs, lobes and airways segmentation using deep-learning algorithms		
	Semi-automatic segmentation of lungs, lobes, and airways.	same		
	Visualization of multi-	same		

	planar reconstructed (MPR) images and 3D rendered images, with color-defined Hounsfield Unit (HU) ranges.			
	Calculation of LAA (Lower Attenuation Area) index with HU density histogram. Volume measurements and percentile index	same		
	Calculation of LAA cluster size distribution with D-slope	same		
	Graphical visualization of the above quantification results for reporting	same		
	Export of quantification results to CSV tables	same		
	Visualization of LAA% for each of 5 lobes	same		
	Measurements of the airway branches, such as, lumen area and wall area	same		
	Analyzes Air Trapping Index by registration of inspiration and expiration data. Could compare both IN/EX after the registration	same		
	Fully automatic INSP/EXP registration (non-rigid elastic) algorithm.	same		
	Quantiatively evaluate fissure integrity ratio and display it by projected fissure image and 3D screen and chart.			Fissure Analysis (fissure integrity) is the percentage of completeness of the fissure. Lung fissures are a doublefold of visceral pleura that either completely or incompletely separates the lungs into lung lobes.

Lung Cancer Screening	Nodule Characteristics	same		
	Automatic calculation of measurements for each segmented nodule ・ Size of the Major axis and Minor axis(mm) ・ Diameter of Major (3D), 2nd Major (3D), Major(2D), Minor(2D) (mm) ・ Volume(mm³) ・ Max, Min, Mean HU of the nodule((HU) Cancer probability (%)	same		
	Comparison and Matching Comparison and matching automatic calculations between each follow-up scan and the baseline scan • Doubling time in days • Indicated the change of the size • Auto generate Lung-RADS	same		
	Loading multiple studies	same		
	Workflow ・ Detect and Segment ・ Comparison and Matching ・ Results ・ Option to integrate with 3rd party CAD which automatically detects the nodules and generate report	same		
	Supporting Low-dose CT	same		
	Reporting results The results include the following. ・ Lung-RADS	same		

	· PANCAN risk calculator Auto detect nodule location by lobe			
	Supports kernel conversion of LAA on LCS Page	-	Noise reduction is performed with the use of pre-trained deep learning models.	
Cardiac (CAC)	Extracting Calcium on Coronary Artery and provides Agatston score, volume score and mass score.	same		
	Automatically segments calcium area of coronary artery based on deep learning.	same		
Thin client service	• Connected from anywhere, anyplace, anytime • Supports mobile view through various mobile devices served by ios and Android. • Comparable with Chrome browser	same		
Easy processing management	Rule-based automatic processing server (APS)	same		

8 PERFORMANCE DATA

8.1 Nonclinical Performance Testing

This Medical device is not new; therefore, a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing

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.

- Unit Test
  Conducting Unit Test using Google C++ Unit Test Framework on major software components identified by

software development team. List of Unit Test includes Functional test condition for software component unit, Performance test condition, and part of algorithm analysis for image processing algorithm.

- System Test

In accordance with the document 'integration Test Cases' discussed in advanced by software development team and test team, test is conducted by installing software to hardware with recommended system specification. Despite Test case recognized in advance was not in existence. New software error discovered by 'Exploratory Test' conducted by test team will be registered and managed as new test case after discussion between development team and test team.

Discovered software error will be classified into 3 categories as severity and managed.

- ✓ Major defects, which 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 aren't impacting the product's intended use. Not significant.

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

- Performance Test
  - Nodule Matching Experiment Using Lung Registration
  - LAA Comparative Experiment for Performance Evaluation of Denoised CT
  - Semi-automatic Nodule Segmentation
  - Brock Model (ask PANCAN) Calculation
  - VDT Calculation
  - Lung RADS Calculation
  - MeVis CAD Integration
  - Validation LAA Analysis
  - Validation LAA Size Analysis
  - Size analysis algorithm of LAA clusters
  - Lung Registration
  - Reliability Test for Airway wall Measurement
  - Fissure Completeness
  - CAC Performance Evaluation of Denoised CT
  - Validation on DVF Size Optimization with Sub-sampling
  - Airway Segmentatation
  - Auto Lung & Lobe Segmentation
  - Kernel Conversion
    - ➢ The LAA result on kernel converted sharp image should have higher reliability with the soft kernel than LAA results on sharp kernel image that is not Kernel Conversion applied. Of the 96 total, 53 are U.S. population and 43 are Korean.
  - Fissure Completeness
    - ➢ Fissure completeness was validated using a total of 129 subjects from TCIA (the Cancer Imaging Archive) LIDC database. The performance was evaluated using Bland Altman plots to assess the fissure completeness performance compared to radiologists. Kappa and ICC were also reported.

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 nonclinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the AVIEW described in this submission is substantially equivalent to the predicate device.