September 17, 2020

Coreline Soft Co., Ltd
Hye Yi Park
Deputy General Manager/Strategic Business Dept.
4, 5F (Yeonnam-dong) 49,
World Cup buk-ro-6-gil,
Mapo-gu, Seoul, Republic of Korea

Re: K200714
Trade/Device Name: AVIEW
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, JAK

Dear Hye Yi Park:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 26, 2020. Specifically, FDA is updating this SE Letter for a typographical error in the trade name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thalia T. Mills, OHT7: Office of In Vitro Diagnostics and Radiological Health, 301-796-6641, thalia.mills@fda.hhs.gov.

Sincerely,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

August 26, 2020

Coreline Soft Co., Ltd
% Hyeyi Park
Deputy General Manager/Strategic Business Dept.
4, 5F (Yeonnam-dong)
49 World Cup buk-ro-6-gil
Mapo-gu, Seoul 03991
REPUBLIC OF KOREA

Re: K200714
Trade/Device Name: AVIEW 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: July 17, 2020
Received: July 20, 2020

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,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200714

Device Name
AVIEW

Indications for Use *(Describe)*
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 also, 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.

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

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K200714

510(k) Summary

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: 03.13.2020

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: LLZ, JAK

3 PREDICATE DEVICE

AVIEW by Coraline Soft Co., Ltd. (K171199)

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

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

4 REFERENCE DEVICE

Imbio CT Lung Density Analysis Software by Imbio LLC (K141069)
Name of Device: Imbio CT Lung Density Analysis Software
Common or Usual Name: Software Accessory to a Computed Tomography Device
Classification Name: System, X-ray tomography, Computed (21CFR 892.1750)
Regulatory Class: II
Product Code: JAK

AVIEW LCS by Coraline Soft Co., Ltd. (K193220)
Name of Device: AVIEW LCS
Common or Usual Name: Image Processing Software
Classification Name: System, image processing, radiological (21CFR 892.2050)
Regulatory Class: II
Product Code: LLZ, JAK

AI-Rad Companion (Cardiovascular) by Siemens Medical Solutions USA, Inc. (K183268)
Name of Device: AI-Rad Companion (Cardiovascular)
Common or Usual Name: AI-Rad Companion (Cardiovascular)
Classification Name: Computed tomography x-ray system (21CFR 892.1750)
Regulatory Class: II
Product Code: JAK, LLZ

Calcium Scoring by Siemens Medical Solutions, Inc. (K990426)
Name of Device: Calcium Scoring
Common or Usual Name: Calcium Scoring
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 DEVICEW DESCRIPTION

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.

- Fully automatic pre-processing
  - Fully automatic lung/lobe segmentation using deep-learning algorithms.
  - Fully automatic airway segmentation using deep-learning algorithms.
  - Fully automatic INSP/EXP registration (non-rigid elastic) algorithm.
- COPD analysis

    - LAA analysis (LAA-950HU for INSP, LAA-856HU for EXP)
    - LAA size analysis (D-Slope)
        - The world-first true 3D analysis of LAA cluster sizes.
    - Precise airway wall thickness measurement
        - Robust measurement using IBHB (Integral-Based Half-BAND) method.
        - Precise AWT-Pi10 calculation from 10 samples per each branch
    - Air-trapping analysis using INSP/EXP registration
    - PRM analysis using INSP/EXP registration (Not available in US)
    - Unique pulmonary vessel analysis method (Lobar-pealing method)
- Easy and comprehensive UI
    - Multiple database management
    - Comprehensive dynamic bull's eye chart and tables.
    - Web-based access to analysis results, including 3D rendering (Thin-client technology)
    - PDF report generation
- Interoperability
    - DICOM 3.0 COMPLIANT: C-STORE, C-FIND, C-MOVE and C-ECHO
    - Resulting images and report can be transferred to PACS through DICOM connection
- Thin client service
    - Connected from anywhere, anyplace, anytime.
    - Supports mobile view through various mobile devices served by iOS and Android.
    - Compatible with Chrome browser
- Research-support
    - 1000+ feature values are exporting for radiomics research.
    - All the segmentation masks are stored in open format (such as Analyze or NifTi)
- Easy processing management
    - Rule-based automatic processing server (APS)
    - Scaling
- Nodule Management
    - Adding nodule by segmentation or by lines.
    - Semi-automatic nodule measurement (segmentation)
    - Maximal plane measure, 3D measure and volumetric measure.
    - Automatic large vessel removal.
    - Provides various features calculated per each nodule.
    - Fully supporting Lung-RADS workflow: US Lung-RADS and KR Lung-RADS.
    - Nodule malignancy score (PANCAN model calculation.)
    - Importing from CAD results.
- Follow-up
    - Automatic retrieving the past data
    - Follow-up support with nodule matching and comparison
    - Automatic calculation of VDT (volume doubling time)
- Lungs, Lobes and Airway segmentation
    - Better segmentation of lungs, lobes and airway based on deep-learning algorithms.
- Automatic nodule detection (CADe)
    - Seamless integration with Mevis Visia (FDA 510(k) Cleared)
- Coronary Artery Calcification
    - Extracts calcium coronary artery and provide Agatston Score, Volume Score and Mass score.
    - Automatically segments calcium area of coronary artery based on deep learning

- Segments and provides overlay of four main artery (right coronary artery, left main coronary, left anterior-descending, and left circumflex artery) and myocardium
- Provides CAC risk based on age and gender.

- Report
  - PDF report generation
  - It saves or sends the pdf report and captured images in DICOM files.
  - Reports are generated using the results of all nodules detected so far (Lung RADS)
- Save Result
  - It saves the results in internal format

6 INDICATIONS FOR USE

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 also, 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.

7 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

AVIEW has the same intended use and the principle of operation and has similar features to the predicate devices. AVIEW (K171199)

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	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
Device Name	**AVIEW 2.0**	**AVIEW**	**Imbio CT Lung Density Analysis Software**	**AVIEW LCS**	**AI-Rad Companion (Cardiovascular)**	**Calcium Scoring**
Classification Name	System, image Processing Radiological	System, image Processing Radiological	Computed Tomography x-ray system	System, image Processing Radiological	Computed Tomography x-ray system	Computed Tomography x-ray system

Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1750	21 CFR 892.2050	21 CFR 892.1750	21 CFR 892.1750
Product Code	LLZ, JAK	LLZ	JAK	LLZ, JAK	JAK	JAK
Review Panel	Radiology	Radiology	Radiology	Radiology	Radiology	Radiology
510k Number	-	K171199	K141069	K193220	K183268	K990426
Indications for use	**AVIEW 2.0** 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 air trapping on lung, 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. **AVIEW** AVEIW provides CT values for pulmonary tissue from CT thoracic datasets. This software can be used to support the physician quantitatively in the diagnosis, followup evaluation and documentation of CT lung tissue images by providing image segmentation of sub-structures in the left and right lung (e.g., the five lobes and airway), volumetric and structural analysis, density evaluations and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data sets. AVEIW is not meant for primary image Interpretation in mammography. **Imbio CT Lung Density Analysis Software** The Imbio CT Lung Density Analysis Software provides reproducible CT values for pulmonary tissue, which is essential for providing quantitative support for diagnosis follow up examinations. The Imbio CT Lung Density Analysis Software can be used to support the physician in the diagnosis and documentation of pulmonary tissue images (e.g., abnormalities) from CT thoracic datasets. Three-D segmentation and isolation of sub-compartments, volumetric analysis, density evaluation, and reporting tools are provided. **AVEIW LCS** AVIEW LCS is intended for the review and analysis and reporting of thoracic CT images for the purpose of 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 measured in 3D for a 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, also integrate with FDA certified Mevis CAD (Computer-aided detection) (K043617) **AI-Rad Companion (Cardiovascular)** AI-Rad Companion (Cardiovascular) is processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of cardiovascular disease. It provides the following functionality: ・ Segmentation and volume measurement of the heart ・ Quantification of the total calcium volume in the coronary arteries ・ Segmentation of the aorta ・ Measurement of maximum diameters of the aorta at typical landmarks ・ Threshold-based highlighting of enlarged diameters The software has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Helathineers, GE Healthcare, Philips, and Toshiba/Canon, Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction form Siemens Healthineers. Only DICOM images of adult patients are considered to be valid input. **Calcium Scoring** From user specified sets of CT cardiac images, Calcium Scoring can be used to; ・ Allow the user to interactively indicate regions of detected calcification ・ To allow the user to allocate each detected region to one of several coronary arteries ・ To estimate algorithmically a score for the amount of detected calcification in each allocated artery ・ To prepare reports including reports including calcium score data, Imagery, ECG traces, Comparison of scroe to cited literature and additional relevant information. The calcium-scoring package is a diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, which is a risk factor for coronary artery disease. Calcium scoring may be used to monitor the progression or regression overtime of the amount or volume of calcium in the coronary arteries, which may be related to the prognosis of a cardiac attack.					
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network
User Interface	Monitor, Mouse,	Monitor, Mouse,	Monitor, Mouse,	Monitor, Mouse,	Monitor, Mouse,	Monitor, Mouse,

	Keyboard	Keyboard	Keyboard	Keyboard	Keyboard	Keyboard
Image Input Sources	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device
Image format	DICOM	DICOM	DICOM	DICOM	DICOM	DICOM
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	Ruler (line and 3D), Tapeline (curve, poly and3D), Angle (3-point, 4point, and 3D), pixel values, area of ROI (rectangle, circle, ellipse), volume	-	Ruler (line and 3D), Tapeline (curve, poly and3D), Angle (3-point, 4point, and 3D), pixel values, area of ROI (rectangle, circle, ellipse), volume	-	-
Image viewing	Axial, sagittal, and coronal image, oblique slice, cube view	Axial, sagittal, and coronal image, oblique slice, cube view	-	Axial, sagittal, and coronal image, oblique slice, cube view	-	-
Image manipulation	Panning, rotating, zooming, windowing, inverting, Coloring, Oblique, Note (text overlay), Coloring	Panning, rotating, zooming, windowing, inverting, Coloring, Oblique, Note (text overlay), Coloring	-	Panning, rotating, zooming, windowing, Coloring, Oblique, Note (text overlay), Coloring	-	-
General Description	**AVIEW 2.0**					
	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 volumetric 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.					
	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.					
	Imbio CT Lung Density Analysis Software					
	The Imbio CT Lung Density Analysis Software (Imbio LDA) IS A SET OF IMAGE POST-PROCESSING ALGORITHMS THAT PERFORM IAMGE SEGMENTATION, REGISTRATION, THRESHOLDING, AND CLASSIFICATION ON ct images of juman lungs. The algorithms within the Imbio CT Lung Density Analysis Software are combined into a single command-line or through scripting. The Imbio CT Lung Density Analysis Software program performs segmentation, then registration, then thresholding and classification. The program reads in DICOM datasets, processes the data, then writes output DICOM files to a specified directory. The Imbio CT Lung Density Analysis Software is a command-line software application that analyzed DICOM CT Lung images datasets and generated reports and DICOM output that show the lungs segmented and overlaid with colorpcodings representing the results of its thresholding and classification rules. It has simple file management functions for input and output, and separate modules that implement the CT image-processing algorithms. Imbio CT Lung Density Analysis Software does not interface directly with any CT or data collection equipment; instead the software imports data files previously generated by such equipment.					
	AVIEW LCS					
	AVIEW LCS is intended for use as diagnostic patient imaging which is intended for the review and analysis of thoracic CT images. Provides following features as semi-automatic nodule measurement (segmentation), maximal plane measure, 3D measure and volumetric measures, automatic nodules detection by integration with 3rd party CAD. Also provide cancer risk based on PANCAN risk 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.					
	AI-Rad Companion (Cardiovascular)					
	In general, AI-Rad Companion (Cardiovascular) is a software only image post-processing application that uses deep learning algorithms to post-process CT data of the thorax. As an update to the previously cleared devices, the following modifications have been made; 1) Modified indication for Use Statement 2) Support of software AI-Rad Companion CT VA10A a) heart segmentation including measurement (modified) b) calcium detection based on deep learning algorithm (modified) c) Aorta segmentation (modified)					

<table>
<tr><td></td><td colspan="6">d) AHA landmarks for labeling and diameter measurement of the aorta, including threshold-based aorta diameter classification (modified)
3) subject device claims list
The subject device AI-Rad Companion (Cardiovascular) is an image processing software that utilizes deep learning algorithms to provide quantitative and qualitative analysis from previously acquired Computed Tomography DICOM image to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of disease of the thorax. The subject devcei support the following device specific functionality.
・ Segmentation and volume measurement of heart
・ Identification and measurement of volume with high Hounsfield values- related to coronary calcification
・ Segmentation of the aorta determination of 9 Landmarks.
・ Computation of cross-sectional MPRs at the 9 landmarks and their maximum diameter
・ Measurement of maximum diameters of the aorta at typical landmakrs.
Threshold-based classification of diameters into different categories</td></tr>
<tr><td></td><td colspan="6">Calcium Scoring</td></tr>
<tr><td></td><td colspan="6">Calcium Scoring is a software package running on the 3Dvirtuoso workstation that allows the user to mark regions of detected calcification in CT cardiac images, to assign each region to a coronary artery, and to calculate the Agatston score and other information from the identified pixels. Film and paper reports of the results can also be prepared. Calcium Scoring is also a cost-effective alternative to Electron Beam CT (EBCT), since it produces calcium scores that correlated to the EBCT's gold standard, but at a much lower cost.</td></tr>
<tr><td>DICOM</td><td>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.</td><td>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.</td><td>Retrieve image data over the network via DICOM</td><td>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.</td><td>Retrieve image data over the network via DICOM</td><td>Retrieve image data over the network via DICOM</td></tr>
<tr><td rowspan="10">Lung Analysis Functions</td><td>Fully automatic lungs, lobes and airways segmentation using deep-learning algorithms</td><td rowspan="2">Semi-automatic segmentation of lungs, lobes and airways.</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Semi-automatic segmentation of lungs, lobes and airways.</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Visualization of multi-planar reconstructed (MPR) images and 3D rendered images, with color-defined Hounsfield Unit (HU) ranges.</td><td>Visualization of multi-planar reconstructed (MPR) images and 3D rendered images, with color-defined Hounsfield Unit (HU) ranges.</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Calculation of LAA (Lower Attenuation Area) index with HU density histogram. Volume measurements and percentile index</td><td>Calculation of LAA (Lower Attenuation Area) index with HU density histogram. Volume measurements and percentile index</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Calculation of LAA cluster size distribution with D-slope</td><td>Calculation of LAA cluster size distribution with D-slope</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Graphical visualization of the above quantification results for reporting</td><td>Graphical visualization of the above quantification results for reporting</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Export of quantification results to CSV tables</td><td>Export of quantification results to CSV tables</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Visualization of LAA% for each of 5 lobes</td><td>Visualization of LAA% for each of 5 lobes</td><td></td><td>-</td><td></td><td></td></tr>
<tr><td>Measurements of the airway branches, such as, lumen area and wall area</td><td>Measurements of the airway branches, such as, lumen area and wall area</td><td></td><td></td><td></td><td></td></tr>
</table>

	Analyzes Air Trapping Index by registration of inspiration and expiration data. Could compare both IN/EX after the registration	-	Imbio provides segmentation of lung and automatied registration of inspiration and expiration image part to classify the analysis by thresholding the CT data. It also provides an interctive visualliztion of the registered pairs to analyze low-density cluster (air trap) and airway analysis.			
	Fully automatic INSP/EXP registration (non-rigid elastic) algorithm.	-	Uses advanced image processing techniques to spatially "register" two CT image of the lungs.			
Lung Cancer Screening	Fully automatic lung/lobe segmentation using deep-learning algorithms	-	-	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(mm^3) ・ Max, Min, Mean HU of the nodule((HU) Cancer probability (%)	-	-	same		
	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 ・ PANCAN risk calculator ・ Auto detect nodule location by lobe	-	-	Same		

Cardiac (CAC)	Extracting Calcium on Coronary Artery and provides Agatston score, volume score and mass score.	-	-	-	Extracting Calcium on Coronary Artery and provides Agatston score and volume score	evaluation and documentation of calcified coronary lesions, calculation of the Agatston equivalent score
	Automatically segments calcium area of coronary artery based on deep learning.				Calcium Detection deep learning-based algorithm	

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
  - Auto Lung & Lobe Segmentation
  - Airway Segmentation
  - Nodule Matching Experiment Using Lung Registration
  - Validation on DVF Size Optimization with Sub-sampling
  - Semi-automatic Nodule Segmentation

- Brock Model (ask PANCAN) Calculation
- VDT Calculation
- Lung RADS Calculation
- Validation LAA Analysis
- Validation LAA Size Analysis
- Size analysis algorithm of LAA clusters
- Lung Registration
- Reliability Test for Airway wall Measurement
- CAC Performance
- Air Trapping Analysis

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.