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, 03991
REPUBLIC OF KOREA

May 5, 2020

Re: K193220
Trade/Device Name: AVIEW LCS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: April 2, 2020
Received: April 6, 2020

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,

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)*

K193220

Device Name

AVIEW LCS

Indications for Use *(Describe)*

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).

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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K193220

510(k) Summary

1 SUBMITTER

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Contact Person: hyeyi. Park
Date Prepared: 11.15.2019

2 DEVICE

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

3 PREDICATE DEVICE

Lung Nodule Assessment and Comparison Option by Philips Medical System Nederland B.V. (K162484)

Name of Device: Lung Nodule Assessment and Comparison Option (LNA)
Common or Usual Name: Lung Nodule Assessment and Comparison Option (LNA)
Classification Name: System, image processing, radiological (21CFR 892.1750)
Regulatory Class: II
Product Code: LLZ, JAK

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

4 REFERENCE DEVICE

Lung Analysis Software by Vital Images, Inc. (K151283)

Name of Device: Lung Analysis Software
Common or Usual Nmae: Radilolgical Image Processing Software
Classification Name: System, Image Processing, Radiological
Regulatory Class: II
Product Code: JAK, LLZ

AVIEW by Coreline 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 reference device has not been subject to a design-related recall

5 DEVICEW DESCRIPTION

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 provides cancer risk based on PANCAN risk 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 is based on type, size, size change and other findings that is reported.

- Nodule measurement
  - 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 such as size, major(longest diameter measured in 2D/3D), minor (shortest diameter measured in 2D/3D), maximal plane, volume, mean HU, minimum HU, maximum HU for solid nodules and ratio of the longest axis for solid to non solid for paritla solid nodules.
  - 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)
- Automatic nodule detection (CADe)
  - Seamless integration with Mevis Visia (FDA 510k Cleared)
- Lungs and lobes segmentation
  - Better segmentation of lungs and lobes based on deep-learning algorithms.
- Report
  - PDF report generation

- It saves or sends the pdf report and captured images in DICOM files.
- It provides structured report including following items such as nodule type, nodule location and, also input finding on nodules.
- Reports are generated using the results of all nodules nodules detected so far (Lung RADS)

- Save Result
  - It saves the results in internal format

6 INDICATIONS FOR USE

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).

7 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE

AVIEW LCS has the same intended use and the principle of operation, and also has similar features to the predicate devices. Lung Nodule Assessment and Comparison Option (LNA) (K162484)
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**
Device Name	**AVIEW LCS**	**Lung Nodule Assessment and Comparison Option (LNA)**	**Lung Analysis Software**	**AVIEW**
Classification Name	System, image Processing Radiological	System, image Processing Radiological	System, image Processing Radiological	System, image Processing Radiological
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ, JAK	LLZ, JAK	LLZ, JAK	LLZ
Review Panel	Radiology	Radiology	Radiology	Radiology
510k Number	-	K162484	K151283	K171199
Indications for use	**AVIEW 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).			
	Lung Nodule Assessment and Comparison Option (LNA)			
	The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. Characterizations include diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.			
	Toshiba's Lung Analysis Software			
	The separately licensed Lung Analysis option is intended for the review and analysis 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. Characterization include diameter, volume and volume over time. The system automatically performs the measurement, allowing lung nodules and measurement to be displayed.			
	AVIEW			
	AVIEW provides CT values for pulmonary tissue from CT thoracic datasets. This software can 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 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. AVIEW is not meant for primary image Interpretation in mammography.			
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
User Interface	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	Monitor, Mouse, 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
Image format	DICOM	DICOM	DICOM	DICOM
Intended body part	Chest	Chest	Chest	Chest
Type of scans	Thoracic CT images	Thoracic CT images	Thoracic CT images	
General Description	**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 provides cancer risk based on PANCAN risk 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 is based on type, size, size change and other findings that is reported.			
	Lung Nodule Assessment and Comparison Option (LNA)			
	The Lung Nodule Assessment and Comparison Option application is intended for use as a diagnostic patient imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed. The user interface and automated tools help to determine growth patterns and compose comparative reviews. The Lung Nodule Assessment and Comparison Option application requires the user to identify a nodule and to determine the type of nodule in order to use the appropriate characterization tool. Lung Nodule Assessment and Comparison Option may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening			
	Lung Analysis Software			
	Lung Analysis aids in measuring and characterizing lung nodules. The interface and automated tools help to efficiently determine growth patterns and compose comparative reviews. Lung Analysis is intended for the review and analysis 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 diameter, volume and volume over time. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed. The Lung Analysis Software requires the user to identify a nodule and to determine whether it is a GGO or solid nodule in order to use the appropriate characterization too.			
	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.			
Key Functions	Providing ray sum image, axial, sagittal, coronal, and oblique planes.	Providing axial, sagittal, coronal, and oblique planes	Providing axial, sagittal, coronal, and oblique planes	Providing ray sum image, axial, sagittal, coronal, and oblique planes
	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction
	Providing VR (Volume render), MIP (Maximum Intensity Projection), MinIP (Minimum Intensity Projection) image	Providing Average, MIP, VIP, MinIP, SurfaceMIP, Vol, Rend.	Providing Average, MIP, VIP, MinIP, SurfaceMIP, Vol, Rend.	Providing VR (Volume render), MIP (Maximum Intensity Projection), MinIP (Minimum Intensity Projection) image
	Changing the color and transparency of the VR image by adjusting the OTF (Opacity Transfer Function) and saving as a preset to easily apply in the VR setting.	Changing the color and transparency of the VR image	Changing the color and transparency of the VR image	Changing the color and transparency of the VR image by adjusting the OTF (Opacity Transfer Function) and saving as a preset to easily apply in the VR setting.
	2D and 3D image	2D and 3D image	2D and 3D image	2D and 3D image

	review	review	review	review
	2D and 3D comparative review	2D and 3D comparative review	2D and 3D comparative review	2D and 3D comparative review
	2D and 3D measurements	2D measurements	2D measurements	2D and 3D measurements
	Segmentation of Lungs and Lobes	Segmentation of lung airway, lungs and lung lobes	Segmentation of lung airway, lungs and lung lobes	Segmentation of lung airway, lungs and lung lobes
	Nodule Characteristics	Nodule Characteristics	Nodule Characteristics	-
	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 (%)	Automatic calculation of measurements for each segmented nodule ・ Short axis-Longest diameter perpendicular to the long axis on the slice(mm) ・ Loung Axis-Longest diameter on an axial slice(mm) ・ Average/Max 3D/Effective diameter(mm) ・ Volume(mm³) Mean densities(HU)	Automatic calculation of measurements for each segmented nodule ・ Volume(mm³) ・ Mean diameter(mm) ・ Maximum diameter(mm) ・ Short axis diameter(mm) ・ Average/minimum/ maximum densities (HU)	
	Comparison and Matching	Comparison and Matching	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	Comparison and matching automatic calculations between each follow-up scan and the baseline scan ・ Doubling time in days ・ Percent (%) and absolute change of all numerical parameters (growth in nodule long axis, short axis, average diameter, max 3D diameter, effective diameter, volume, mean HU)	Comparison and matching automatic calculations between each follow-up scan and the baseline scan ・ Elapsed time in days ・ Doubling time in days Percent (%) growth in nodule volume	-
	Loading multiple studies	Loading multiple studies Up to 3 studies	Loading multiple studies Up to 3 studies	-
	Workflow ・ Detect and Segment ・ Comparison and Matching	Workflow ・ Detect and Segment ・ Comparison and Matching ・ Results	Workflow ・ Detect and Segment ・ Point-and-click detection ・ Automated	-

	・ Results Option to integrate with 3rd party CAD which automatically detects the nodules and generate report.		contouring ・ Automated measurements ・ Manual correction	
	Supporting Low-dose CT	Supporting Low-dose CT	Supporting Low-dose CT	-
	Reporting results The results include the following. ・ Lung-RADS ・ PANCAN risk calculator ・ Auto detect nodule location by lobe	Reporting results The results include the following. ・ Patient related information ・ Dictation Table with Nodule result table and additional findings ・ Lung-RADS ・ Risk Calculator	Reporting results The results include the following. ・ Dictation Table with Nodule result table ・ Lung-RADS ・ Fleischer Criteria	-
	Printing Option	Printing Option	Printing Option	Printing Option

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.

- Nodule Matching test with Lung Registration
  Experiments to check the accuracy of Nodule-Matching using Lung Registration Result in LungScreen Followup Study and to check the applicability of Registry
  Based on the experimented data deployed, the steps below are performed for all 28 location.
  1. Enter the Nodule position of the Fixed image
  2. Convert to the position of the moving image using DVF
  3. Measure the Voxel Distance error between the converted position and the Nodule position of the Moving image.
  4. Start-up verification of the cross-sectional images of the position and the converted position in the Fixed, Moving images.

- Validation on DVF Size Optimization with Sub-sampling test
  To reduce the capacity of DVF calculated after LungRegistration, check the accuracy level of loss when using DVF subsampling and check the possibility
  For each Lung Part, three (Rigid, NonRigid, and LevelSet) DVF files are calculated for each Left and Right Lung. Because each DVF has about 600MB of files size, you will use 3.6GB (2*3*600MB) per case. Therefore, accuracy needs to be explored how to optimize the size of the DVF at the expense of the loss.
  Based on the experimental data deployed, the steps below ae performed for all 28 locations.
  1. Enter the Nodule position of the Fixed image.
  2. Use DisplacementVector placed on above position and replace with the Moving image.
  3. Convert to the position of the moving image using the Mean DisplacementVector in the 3x3x3 area around that location
  4. Measure the Voxel Distance error between each converted position and the Nodule position of the Moving image.
  5. Measure the error of each converted position

- Semi-automatic Nodule Segmentation
  In order to check the accuracy of the measured length and volume value in the node added by Segmentation.
  Create a sphere with a radius of 2mm, 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm, 10mm.
  Providing test function to read measurement of split decision using the node segmentation function.
  Standard judgment:
  The measured length should be less than one voxel size compared to the size of the sphere produced.
  The measured volume should be within 10 error compared to the volume of the sphere created.

- Mevis CAD Integration test
  Confirm Data Transfer and CAD Results SR DICOM Analysis.
  1. Confirm if CT DIOM is sent from AVIEW to MeVis CAD
  2. Confirm that the CAD result SR DICOM is sent from the MeVis CAD to the AVIEW

3. Confirm that it is displayed on the AIVEW Lung Screen by analyzing the contents of the MeVis CAD result SR DIOM

Install AVIEW and MeVis CAD software on each of the two PCs, and set up each environment

- Brock Score (aka. PANCAN) Risk Calculation test
  Generate some sample data, conduct a unit test by comparing the calculate value calculated in a separate Excel sheet with the result value of the implemented code.
  Summary of both publications related to this function: 'Probability of Cancer in Pulmonary Nodules Detected on First Screening CT' and 'The Vancouver Lung Cancer Risk Prediction Model: Assessment by Using a Subset of the National Lung Screening Trial Cohort' concludes that the risk calculator yielded a high discriminant value, which supports the user of risk calculator method as a valuable approach to distinguish between benign and malignant nodules.
  Test Data used for each paper were as below
  - Former paper used PanCan data set, 187 persons had 7008 nodules, of which 102 were malignant, and in the BCCA data set, 1090 persons had 5021 nodules, of which 42 were malignant.
  - The latter used 4431 nodules (4315 benign nodules and 116 malignant nodules of NLST data)

- VDT Calculation test
  Confirmed that the VDT calculation is going well by using unit tests.

- Lung RADS Calculation test
  Test and verify 10 cases were extracted from the Lung-RADS survey table provided by the Korean Society of Thoracic Radiology.
  Confirm that it was implemented in accordance with Lung-RADS regulations by using unit tests.

- Performance test
  In order to check whether the non-functional requirement indicated in section 'Performance and Non-Functional Requirements is satisfied, operate a test according to the performance evaluation standard and method that has been determined with prior consultation between software development team and testing team

- Auto segmentation (based on deep-learning algorithms) test
  Assessment method on Koeran Data
  - Chest CT data taken with 192 suspected COPD patients.
  - Automatic segmentation of lung and lobe is applied using AVIEW LCS to generate segmentation results.
  - The results of auto-segmentation are identified by a specialist and radiologist and classified as 0 (Not good), 1 (need adjustment), and 2(very good)

  Assessment method on NLST Data
  - 80 patient's Chest CT data who were enrolled in NLST.
  - Automatic segmentation of lung and lobe is applied using AVIEW to generate segmentation results.
  - Manual segmentation of lung and lobe is performed by experienced radiolograhper and confirmed by experienced radiologist.
  - The dice similarity coefficient is performed to check how similar they are.

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 LCS described in this submission is substantially equivalent to the predicate device.