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

October 16, 2020

Re: K201710
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: June 22, 2020
Received: September 14, 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)*
K201710

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), Lung-RADS (classification proposed to aid with findings) and CAC score and LAA analysis. 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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006_510(k) Summary

CORELINE

510(k) Summary

1 SUBMITTER

K201710

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Phone: 82.2.517.7321
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Contact Person: hyeyi. Park
Date Prepared: 06.22.2020

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

AVIEW LCS by Coreline 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

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

4 REFERENCE 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

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

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

All reference devices have 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.

- Easy processing management
  - Rule-based automatic processing server (APS)
- Thin client service
  - Connected from anywhere, anyplace, anytime.
  - Support mobile view through various mobile device served by Ios and Android.
  - Compatible with Chrome browser
- 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
  - Fully supporting Lung-RADS workflow: US Lung-RADS and KR Lung-RADS.
  - Nodule malignancy score (PANCAN model) calculation.
  - Importing from CAD results
- CAC, LAA on LC
  - Displays CAC score which was analyzed
  - Displays LAA available which was analyzed

- 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.
  - 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), Lung-RADS (classification proposed to aid with findings) and CAC score and LAA analysis. 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**	**AVIEW LCS**	**Lung Nodule Assessment and Comparison Option (LNA)**	**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, JAK
Review Panel	Radiology	Radiology	Radiology	Radiology
510k Number	-	K193220	K162484	K200714
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), Lung-RADS (classification proposed to aid with findings) and CAC score and LAA analysis. 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).			
	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.			
	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 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.			
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 Soures	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	CT	CT	CT	CT
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 columetric 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.			
	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 columetric 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			
	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.			
Key Functions	Providing ray sum image, axial, sagittal, coronal, and oblique planes.	same	Providing axial, sagittal, coronal, and oblique planes	same
	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction Providing VR (Volume render), MIP (Maximum Intensity Projection), MinIP (Minimum Intensity Projection) image	same	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction Providing Average, MIP, VIP, MinIP, SurfaceMIP, Vol, Rend.	same
	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	same	Changing the color and transparency of the VR image	same
	2D and 3D image review	same	2D and 3D image review	same
	2D and 3D comparative review	same	2D and 3D comparative review	same
	2D and 3D measurements	same	2D measurements	same
	Segmentation of Lungs	same	Segmentation of lung	same

	and Lobes		airway, lungs, and lung lobes	
	Nodule Characteristics	same	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(mm^3) ・ Max, Min, Mean HU of the nodule((HU) ・ Cancer probability (%)	same	Automatic calculation of measurements for each segmented nodule ・ Short axis-Longest diameter perpendicular to the long axis on the slice(mm) ・ Long Axis-Longest diameter on an axial slice(mm) ・ Average/Max 3D/Effective diameter(mm) ・ Volume(mm^3) Mean densities(HU)	same
	Comparison and Matching	same	Comparison and Matching	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	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)	same
	Loading multiple studies	same	Loading multiple studies Up to 3 studies	same
	Workflow ・ Detect and Segment ・ Comparison and Matching ・ Results ・ Option to integrate with 3rd party CAD which automatically detects the nodules	Workflow ・ Detect and Segment ・ Comparison and Matching ・ Results ・ Option to integrate with 3rd party CAD which	Workflow ・ Detect and Segment ・ Comparison and Matching ・ Results	Workflow ・ Detect and Segment ・ Comparison and Matching ・ Results ・ Option to integrate with 3rd party CAD which

	and generate report ・ Displays CAC/LAA result analyzed by AVIEW	automatically detects the nodules and generate report		automatically detects the nodules and generate report
	Supporting Low-dose CT	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	Reporting results The results include the following. ・ Patient related information ・ Dictation Table with Nodule result table and additional findings ・ Lung-RADS ・ Risk Calculator	same
	Printing Option	same	Printing Option	same
Thin client service	・ Connected from anywhere, anyplace, anytime ・ Supports mobile view through various mobile devices served by ios and Android. ・ Compartible 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.

8.2.1 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.

8.2.2 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 are not impacting the product's intended use. Not significant.

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

8.2.3 Performance Test

- DICOM Test Report for AVIEW LCS
- Performacne test report for AVIEW LCS
- AVIEW LCS Integration Test Report
- AVIEW LCS Thin Client Server Compatibility Test Report

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.