Coreline Soft Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consulting
LK Consulting Group USA, Inc
690 Roosevelt
IRVINE, CA 92620

October 31, 2018

Re: K171199
Trade/Device Name: AVIEW
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 9, 2018
Received: October 12, 2018

Dear Priscilla Chung:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

Digitally signed by Michael D. O'hara -S
Date: 2018.10.31 16:54:04 -04'00'

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171199

Device Name
AVIEW

Indications for Use *(Describe)*
AVIEW 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. AVIEW is not meant for primary image Interpretation in mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(K171199)

1. **Date:** 10/09/2018

2. **Applicant / Submitter**

Coreline Soft Co., Ltd.
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3. **U.S. Designated Agent**

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4. **Trade/Proprietary Name:**

AVIEW

5. **Common Name:**

Image Processing Software

6. **Classification:**

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

7. **Device 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.

8. Indication for Use:

AVIEW 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. AVIEW is not meant for primary image Interpretation in mammography.

9. Predicate Device:

- Primary Predicate Device: Vitrea CT Lung Density Analysis Software (K151919)
- Reference Predciate Device: Vitrea, Version 7.0 Medical image Processing Software (K150258)

10. Substantial Equivalence:

AVIEW has the same intended use and the principle of operation, and also has similar features to the predicate devices, Vitrea (K150258 and K151919).
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.

	Subject Device	**Primary Predicate Device**	**Reference Device**
Device Name	AVIEW	Vitrea CT Lung Density Analysis Software	Vitrea, Version 7.0 Medical image Processing Software
Classification Name	System, Image Processing, Radiological	System, X-ray, Tomography, Computed	System, Image Processing, Radiological
Regulatory Number	21 CFR 892.2050	21 CFR 892.1750	21 CFR 892.2050
Product Code	LLZ	JAK	LLZ
Classification	Class II	Class II	Class II
Review Panel	Radiology	Radiology	Radiology
510K number	K171199	K151919	K150258
Indications for Use	AVIEW provides CT values for pulmonary tissue from CT thoracic datasets. This software	The Vitrea Lung Density Analysis software provides CT values for the pulmonary tissue from	Vitrea is a medical diagnostic system that allows the processing, review, analysis,

	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. AVIEW is not meant for primary image Interpretation in mammography.	CT thoracic datasets. Three-dimensional(3D) segmentation of the left lung and right lung, volumetric analysis, density evaluation and reporting tools are integrated in a specific workflow to offer the physician a quantitative support for diagnosis and follow-up evaluation of lung tissue images.	communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea 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
Operation System	Microsoft Window 7, 8, 10	Microsoft Window XP, Window VISTA, Window 7, 8	Microsoft Window XP, Window VISTA, Window 7, 8
User Interface	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 digital cameras or card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device
32 bit / 64 bit	64 bit	32 / 64 bit	32 / 64 bit
Image format	DICOM	DICOM	DICOM
Image Measurement Tools	Ruler (line and 3D), Tapeline (curve, poly and 3D), Angle (3-point, 4 point, and 3D), pixel values, area of ROI (rectangle, circle, ellipse), volume	Ruler (linear), Tapeline(curve), Angle (3-point, 4 point, and 3D), pixel values, area of a region of interest,	Ruler (linear), Tapeline(curve), Angle (3-point, 4 point, and 3D), pixel values, area of a region of interest,
Image viewing	Axial, sagittal, and coronal image, oblique slice, cube view	Axial, sagittal and coronal images, oblique slice, cube view	Axial, sagittal and coronal images, oblique slice, cube view
Image manipulation	Panning, rotating, zooming, windowing, inverting, Coloring, Oblique, Note (text overlay), Coloring	Panning, rotating, zooming, windowing, inverting, text overlay, volume of interest overlay	Panning, rotating, zooming, windowing, inverting, text overlay, volume of interest overlay

	(volume of interest overlay)		
General Description	AVIEW is an image processing software as a medical device. It assists in analyzing pulmonary CT datasets and displaying the analysis results.	Vitrea CT Lung Density Analysis assists in analyzing lung densities and volumes. It semi-automatically segments lung tissues with quantifiable controls and renderings to aid communication with the pulmonologist.	Vitrea is a medical diagnostic system that allows the processing, review, analysis, communication, and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.
DICOM	This receives DICOM data from CT by DICOM communication Conducts DICOM data communication with PACS. It also imports DICOM file directly, saves by using export function.	Retrieve image data over the network via DICOM	Retrieve image data over the network via DICOM
Lung Analysis Functions	Semi-automatic segmentation of lungs, lobes and airways	Semi-automatic right lung, left lung, and airway segmentation	N/A
	Visualization of multi-planar reconstructed (MPR) images and 3D rendered images, with color-defined Hounsfield Unit (HU) ranges	Visualization of lung density with color-defined Hounsfield Unit (HU) range	
	Calculation of LAA (Lower Attenuation Area) index with HU density histogram, volume measurements and percentile index	Lung density result quantification with HU density range, volume measurements, lung density index, and the PD15% measurement	
	Calculation of LAA cluster size distribution with D-slope	Density graph/histogram of the classified lung voxels' relative frequencies	
	Graphical visualization of the above quantification results for reporting	Overlay of density quantification results and density graph histogram for reporting	
	Export of quantification results to CSV tables	Export of density values and curves to CSV tables or copy to clipboard for insertion into a report	
	Visualization of LAA% for each of 5 lobes	Comparison of upper and lower lung density index ratios	
	Measurements of the airway branches, such as, lumen area and wall area		

11. Technological Characteristics:

AVIEW is a software device that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software tools are dependent on the interpretation of trained and licensed radiologists, clinicians and referring physicians as an adjunctive to standard radiology practices for diagnosis.

12. Performance Data:

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. A summary of the conducted tests is as below:

- Unit test
- System test
- DICOM test
- LAA analysis test
- LAA size analysis test
- Airway wall measurement test
- Reliability test
- CT image compatibility test

13. Conclusion:

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.