March 29, 2024

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, KOREA, SOUTH

Re: K233211
Trade/Device Name: AVIEW CAC
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, JAK
Dated: February 23, 2024
Received: February 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233211

Device Name
AVIEW CAC

Indications for Use *(Describe)*
AVIEW CAC provides quantitative analysis of calcified plaques in the coronary arteries using non-contrast/non-gated Chest CT scans. It enables the calculation of the Agatston score for coronary artery calcification, segmenting and evaluating the right coronary artery and left coronary artery. Also provide risk stratification based on calcium score, gender, and age, offering percentile-based risk categories by established guidelines. Designed for healthcare professionals, including radiologists and cardiologists, AVIEW CAC supports storing, transferring, inquiring, and displaying CT data sets on-premises, facilitating access through mobile devices and Chrome browsers. AVIEW CAC analyzes existing non-contrast/non-gated Chest CT studies that include the heart of adult patients above the age of 40. Also, the device's use should be limited to CT scans acquired on General Electric (GE) or its subsidiaries (e.g., GE Healthcare) equipment. Use of the device with CT scans from other manufacturers has not been validated or recommended.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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: 03.28.2024

2 DEVICE

Name of Device: AVIEW CAC
Common or Usual Name: Image Processing Software
Classification Name: Medical Image Management and Processing System (21CFR 892.2050)
Regulatory Class: II
Product Code: QIH, JAK

3 PREDICATE DEVICE

AVIEW by Coraline Soft Co., Ltd. (K214036)

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

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

4 REFERENCE DEVICE

HealthCCSng by Zebra Medical Vision Ltd.(K210085)

Name of Device: HealthCCSng
Common or Usual Name: Image Processing Software
Classification Name: Medical Image Management and Processing System (21CFR 892.1750)
Regulatory Class: II
Product Code: JAK

5 DEVICE DESCRIPTION

The AVIEW CAC is a software product that can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0, the digital image and communication standard in medicine. It also offers functions such as reading, manipulation, analyzing, post-processing, saving, and sending images by using software tools. And is intended for use as a quantitative analysis of CT scanning. It also provides a calcium score by automatically analyzing coronary arteries from the segmented arteries.

6 INDICATIONS FOR USE

AVIEW CAC provides quantitative analysis of calcified plaques in the coronary arteries using non-contrast/non-gated Chest CT scans. It enables the calculation of the Agatston score for coronary artery calcification, segmenting and evaluating the right coronary artery and left coronary artery. Also provide risk stratification based on calcium score, gender, and age, offering percentile-based risk categories by established guidelines. Designed for healthcare professionals, including radiologists and cardiologists, AVIEW CAC supports storing, transferring, inquiring, and displaying CT data sets on-premises, facilitating access through mobile devices and Chrome browsers. AVIEW CAC analyzes existing non-contrast/non-gated Chest CT studies that include the heart of adult patients above the age of 40. Also, the device's use should be limited to CT scans acquired on General Electric (GE) or its subsidiaries (e.g., GE Healthcare) equipment. Use of the device with CT scans from other manufacturers has not been validated or recommended.

7 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE

AVIEW CAC has the same intended use and the principle of operation and has similar features to the predicate devices. AVIEW (K214036)

There might be slight differences in features and menu, but these differences between the predicate device and the proposed device are not so significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation and verification tests, we conclude that the proposed device is substantially equivalent to the predicate devices.

Characteristic	Subject Device	Predicate Device	Reference Device
Device Name	**AVIEW CAC**	**AVIEW**	**HealthCCSng**
Classification Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Medical Image Management and Processing System
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1750
Product Code	QIH, JAK	QIH, JAK	JAK
Review Panel	Radiology	Radiology	Radiology
510k Number	-	K214036	K210085
Indications for use	**AVIEW CAC**		
	AVIEW CAC provides quantitative analysis of calcified plaques in the coronary arteries using non-contrast/non-gated Chest CT scans. It enables the calculation of the Agatston score for coronary artery calcification, segmenting and evaluating the right coronary artery and left coronary artery. Also provide risk stratification based on calcium score, gender, and age, offering percentile-based risk categories by established guidelines. Designed for healthcare professionals, including radiologists and cardiologists, AVIEW CAC supports		

	storing, transferring, inquiring, and displaying CT data sets on-premises, facilitating access through mobile devices and Chrome browsers. AVIEW CAC analyzes existing non-contrast/non-gated Chest CT studies that include the heart of adult patients above the age of 40. Also, the device's use should be limited to CT scans acquired on General Electric (GE) or its subsidiaries (e.g., GE Healthcare) equipment. Use of the device with CT scans from other manufacturers has not been validated or recommended.
	AVIEW
	AVIEW provides CT values for pulmonary tissue from CT thoracic and cardiac datasets. This software can be used to support the physician providing quantitative analysis of CT images by image segmentation of sub-structures in the lung, lobe, airways, fissures completeness, cardiac, density evaluation, and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data set on-premises and as a cloud environment to allow users to connect by various environments such as mobile devices and Chrome browsers. Converts the sharp kernel to soft kernel for quantitative analysis of segmenting low attenuation areas of the lung. Characterizing nodules in the lung in a single study or over the time course of several thoracic studies. Characterizations include nodule type, location of the nodule, and measurements such as size (major axis, minor axis), estimated effective diameter from the volume of the nodule, the volume of the nodule, Mean HU(the average value of the CT pixel inside the nodule in HU), Minimum HU, Max HU, mass(mass calculated from the CT pixel value), and volumetric measures(Solid major; length of the longest diameter measure in 3D for a solid portion of the nodule, Solid 2nd Major: The size of the longest diameter of the solid part, measured in sections perpendicular to the Major axis of the solid portion of the nodule), VDT (Volume doubling time), and Lung-RADS (classification proposed to aid with findings.). The system automatically performs the measurement, allowing lung nodules and measurements to be displayed and, integrate with FDA certified Mevis CAD (Computer aided detection) (K043617). It also provides the Agatston score, volume score, and mass score by the whole and each artery by segmenting four main arteries (right coronary artery, left main coronary, left anterior descending, and left circumflex artery). Based on the calcium score provides CAC risk based on age and gender. The device is indicated for adult patients only.
	HealthCCSng
	The HealthCCSng device is intended for use as a non-invasive post-processing software to evaluate calcified plaques in the coronary arteries, which present a risk for coronary artery disease. The software generates an estimated coronary artery calcium detection category. The HealthCCSng device analyzes existing non-cardiac-gated CT studies that include the heart of adult patients above the age of 30. The device generates a three-category output representing the estimated quantity of calcium detected together with preview axial images of the detected calcium meant for informational purposes only. The device output will be available to the radiologist as part of their standard workflow. The HealthCCSng results are not intended to be used on a stand-alone basis for risk attribution, clinical decision-making or otherwise preclude clinical assessment of CT studies
General Description	**AVIEW CAC**
	The AVIEW CAC is a software product that can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0, the digital image and communication standard in medicine. It also offers functions such as reading, manipulation, analyzing, post-processing, saving, and sending images by using software tools. And is intended for use as a quantitative analysis of CT scanning. It also provides a calcium score by automatically analyzing coronary arteries from the segmented arteries.

	AVIEW The AVIEW is a software product that can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0, the digital image and communication standard in medicine. It also offers functions such as reading, manipulation, analyzing, post-processing, saving, and sending images by using software tools. And is intended for use as a quantitative analysis of CT scanning. It provides the following features such as segmentation of lung, lobe, airway, fissure completeness, semi-automatic nodule management, maximal plane measure, 3D measures and volumetric measures, automatic nodule detection by integration with 3rd party CAD. It also provides the Brocks model, which calculates the malignancy score based on numerical or Boolean inputs. Follow-up support with automated nodule matching and automatically categorize Lung-RADS score, which is a quality assurance tool designed to standardize lung cancer screening CT reporting and management recommendations that are based on type, size, size change, and other findings that are reported. It also provides a calcium score by automatically analyzing coronary arteries from the segmented arteries		
	HealthCCSng HealthCCSng product is a software device that automatically estimates the coronary artery calcium category from non-cardiac-gated adult CT scans. The product is aimed to leverage the high utilization of CT scans in the medical care environment (both inpatient and outpatient), including lung cancer screening programs, in order to automatically detect calcification in the coronary arteries of patients in an opportunistic manner. Zebra's HealthCCSng product analyzes cases using an artificial intelligence algorithm for the automated detection and estimation of coronary calcium and outputs a result for review by the radiologist. The device works in parallel to and in conjunction with the standard of care workflow. The final diagnosis is made by the radiologist after reviewing the scan independently of the software. The device is intended for use by the radiologists as a non-diagnostic analysis software in conjunction with additional patient information and professional judgment. HealthCCSng receives a non-cardiac-gated CT study from the storage application, Zebra's Imaging Analytics Platform (IMA). For each CT study received, the software shall validate there is at least one compliant series in which the entire heart is present, and perform an analysis. For each compliant study, the software shall output: 1. Estimated Coronary Calcium Detection, based on the measurement of calcium deposits in the coronary arteries. 2. A corresponding Estimated Coronary Calcium Detection Category, based on the Estimated Coronary Calcium measurement.		
Platform	IBM-compatible PC or PC network	same	
User Interface	Monitor, Mouse, Keyboard	same	
Image Input Sources	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	same	
Image format	DICOM	same	same
Image Measurement Tools	Ruler (line and 3D), Tapeline (curve, poly and3D), Angle (3-point, 4point, and 3D), pixel values, area of ROI (rectangle, circle, ellipse), volume	same	

Image viewing	Axial, sagittal, and coronal image, oblique slice, cube view	same	
Image manipulation	Panning, rotating, zooming, windowing, inverting, Coloring, Oblique, Note (text overlay), Coloring	same	
DICOM	This receives DICOM data from CT by DICOM communication Conducts DICOM data communication with PACS. It also imports DICOM file directly, saves by using export function.	same	
CAC	Extracting Calcium on Coronary Artery and provides Agatston score.	Extracting Calcium on Coronary Artery and provides Agatston score, volume score and mass score.	Agatston equivalent CAC risk category, based on the Agatston method
	Automatically segments the calcium area of the coronary artery based on deep learning.	same	Not applicable
Contrast	Non-contrast	Non-contrast	Non-contrast
Supported CT scan	Non-contrast/non-gated Chest CT	Cardiac CT	Non-Cardiac gated CT scan
Guideline and Risk Percentile	MAYO-1999 SCCT/STR-2016 UserCustom AMJ-2001 MESA-2006	MAYO-1999 SCCT/STR-2016	-
Thin client service	• Connected from anywhere, anyplace, anytime. • Supports mobile view through various mobile devices served by ios and Android. Comparable with Chrome browser	same	
Easy processing management	Rule-based automatic processing server (APS)	same	

8 PERFORMANCE DATA

8.1 Nonclinical Performance Testing

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

device. The substantial equivalence of the device is supported by the non-clinical testing.

8.2 Software Verification and Validation

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

- Unit Test

  Conducting Unit Test using Google C++ Unit Test Framework on major software components identified by software development team. List of Unit Test includes Functional test condition for software component unit, Performance test condition, and part of algorithm analysis for image processing algorithm.

- System Test

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

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

  - ✓ Major defects, which are impacting the product's intended use and no workaround is available.
  - ✓ Moderate defects, which are typically related to user-interface or general quality of product, while workaround is available.
  - ✓ Minor defects, which aren't impacting the product's intended use. Not significant.

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

- Regression Test

  Regression test aims to ensure the quality and stability of the product by reconfirming the proper functioning of existing features through the selection of either all or specific test cases that have been previously executed.

- Performance Test

  - Performance test on Chest CT
    - ➢ This test comprised two distinct components. First, we evaluated the agreement in coronary calcium scoring between the subject device and the ground truth. Second, we investigated the concordance in coronary calcium scoring between the subject device and the predicate device. We used a total of 150 CSCT (gated) cases and a total of 150 Chest CT (non-gated) cases and assess the performance of AVIEW CAC in measuring coronary calcium using the Agatston Score on non-contrast chest CT scans. Also, the device's performance was validated with GE CT.
      - Performance testing results

		Ground Truth		Predicate	
		ICC (95% CI)	**p-value(>0.8)**	**ICC (95% CI)**	**p-value(>0.8)**
Total (n=150)	Total	0.896(0.857,0.925)	<.001	0.939(0.916,0.956)	<.001
	LCA	0.927(0.899,0.947)	<.001	0.955(0.938,0.968)	<.001
	RCA	0.840(0.778,0.884)	<.001	0.887(0.844,0.918)	<.001

- MI functionality test report
  - Using the 280 datasets collected from multiple institutions, the correlation coefficient between the AVIEW CAC automatic analysis results of the chest CT based on the heart CT and the Agatston scores was over 90%, indicating reliability in evaluating Agatston scores for chest CT images.

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