October 16, 2026

Coreline Soft Co., Ltd.
Hyeyi Park
Director
12, Donggyo-Ro 19-Gil,
Mapo-Gu, Seoul, 04001 KOR

Re: K260391
Trade/Device Name: AVIEW Aorta Metrics
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: September 6, 2026
Received: September 8, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,



Jessica Lamb, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260391

Please provide the device trade name(s).

AVIEW Aorta Metrics

Please provide your Indications for Use below.

AVIEW Aorta Metrics is software intended for use in adult patients 18 years of age or older that automatically segments the aorta and measures the aortic diameter by anatomical region using an AI-trained model from CT images.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

1 SUBMITTER

Coreline Soft Co., Ltd.
12, Donggyo-ro 19-gil, Mapo-gu, Seoul, Republic of Korea.

Phone: 82.2.517.7321
Fax: 82.2.571.7324

Contact Person: hyeyi. Park

2 DEVICE

Name of Device: AVIEW Aorta Metrics
Classification Name: Computed Tomography X-ray System (21CFR 892.1750)
Regulatory Class: II
Product Code: JAK

3 PREDICATE DEVICE

AI-Rad Companion (CardioVascular) by Siemens Medical Solutions U.S.A.

Name of Device: AI-Rad Companion (CardioVascular)
510k Number: K222360
Classification Name: Computed Tomography X-Ray System (21CFR 892.1750)
Regulatory Class: II
Product Code: JAK

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

4 DEVICE DESCRIPTION

AVIEW Aorta Metrics automatically segments the aorta using an aorta segmentation model learned with FCN (Full Convolutional Network) Deep Learning AI from chest CT images. Using the aorta segmentation result and CT images together, the aorta area segmentation model learned with FCN Deep Learning AI is used to automatically segment and measure the diameter. This product complies with the DICOM standard and can be linked to a picture storage and communication system (PACS). The device is intended to be used with a cleared AVIEW platform.

5 INDICATIONS FOR USE

AVIEW Aorta Metrics is software intended for use in adult patients 18 years of age or older that automatically segments the aorta and measures the aortic diameter by anatomical region using an AI-trained model from CT images.

6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE

Characteristic	Subject Device	Predicate Device
Device Name	**AVIEW Aorta Metrics**	**AI-Rad Companion (CardioVascular)**
Classification Name	Computed Tomography X-ray System	Computed Tomography X-Ray System
Regulatory Number	892.1750	892.1750
Product Code	JAK	JAK
Review Panel	Radiology	Radiology
510k Number	-	K222360
Indications for use	AVIEW Aorta Metrics is software intended for use in adult patients 18 years of age or older that automatically segments the aorta and measures the aortic diameter by anatomical region using an AI-trained model from CT images.	AI-Rad Companion (Cardiovascular) is image processing software that provides quantitative and qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of cardiovascular diseases. It provides the following functionality: - Segmentation and volume measurement of the heart - Quantification of the total calcium volume in the coronary arteries - Segmentation of the aorta - Measurement of maximum diameters of the aorta at typical landmarks - Threshold-based highlighting of enlarged diameters The software has been validated for non-cardiac chest CT data with filtered backprojection reconstruction from Siemens Healthineers, GE Healthcare, Philips, and Toshiba/Canon. Additionally, the calcium detection feature has been validated on non-cardiac chest CT data with iterative reconstruction from Siemens Healthineers. Only DICOM images of adult patients are considered to be valid input.
General Description	AVIEW Aorta Metrics automatically segments the aorta using an aorta segmentation model learned with FCN (Full Convolutional Network) Deep Learning AI from chest CT images. Using the aorta segmentation result and CT images together, the aorta area segmentation model learned with FCN Deep Learning AI is used to automatically segment and measure the diameter. This product complies with the DICOM standard and can be linked to a picture storage and communication system (PACS). The device is intended to be used with a cleared AVIEW platform.	AI-Rad Companion (Cardiovascular) SW version VA20 is an enhancement to the previously cleared device AI-Rad Companion (Cardiovascular) K183268 that utilizes machine and deep learning algorithms to provide quantitative and qualitative analysis to computed tomography DICOM images to support qualified clinicians in the evaluation and assessment of cardiovascular diseases.
Aorta segmenation	Aorta Segementation with deep learning-based algorithm.	Aorta Segementation with deep learning-based algorithm.

Landmark detection	Landmark Detection with deep learning-based algorithms, 3 AHA positions.	Landmark Detection with deep learning-based algorithms, 9 AHA positions.
Aorta diameter measurement	Automatically measures the aorta diameter for each zone.	Aorta diameter measurements at nine predefined locations according to the AHA guidelines and at the locations of the maximum diameter of the ascending and descending aorta.
Aorta categories	Categorization of diameter measurements at locations according to the AHA guidelines and at locations of the maximum diameter of ascending and descending aorta.	Categorization of diameter measurements at locations according to the AHA guidelines and at locations of the maximum diameter of ascending and descending aorta.
Image format	DICOM	DICOM
Outputs	- Visualization of aorta and aorta zone areas - Segmentation of aorta and aorta zone areas - Provides measured diameter values (max diameter) for each aorta zone	- Segmentation and volume measurement of the heart - Quantification of the total calcium volume in the coronary arteries - Segmentation of the aorta - Measurement of maximum diameters of the aorta at typical landmarks - Threshold-based highlighting of enlarged diameters
Modality	Non-enhanced chest CT	Non-enhanced cheset CT
Deployment	Cloud and on-premise deployments	Cloud and Edge (on-premise) deployments

7 PERFORMANCE DATA

7.1 Standalone Test

To evaluate the performance of AVIEW Aorta Metrics, the results for aortic segmentation and diameter measurement were analyzed. All DSC results for segmentation accuracy met the established pass criteria. For maximum-diameter measurement performance, based on inter-reader variability assessment, 95% LoAs were established at ±4.61 mm, and 92.33% of the overall measurements from the AVIEW Aorta Metrics fell within the LoA. The subject device yielded an overall MAE of ≤ 1.95 mm (95% CI: 1.78–2.12) and a bias of -1.58 mm (95% CI: -1.79 to -1.37), demonstrating comparable performance to the predicate device (91.9% of the measurements provided by the predicate device were found to lie within the LoA, with a bias within ±1.5 mm, 95% CI: 1.2 mm – 1.8 mm / MAE ≤ 1.8 mm, 95% CI: 1.44 mm – 2.23 mm).

7.2 Software Verification and Validation

7.2.1 Unit Test

- Perform unit tests according to software requirements.
- If every unit test contents are 100% pass, unit test is done.
- It was confirmed that Every unit test verification contests are 100% pass.

7.2.2 System Test

- Total 100 tests were performed, if every test contets are 100% pass, system test is done.
- It is confirmed that every system test verification contets were 100% pass.

7.2.3 Performance Test

- System availability test
- Image storage error test
- Data deleting preventions on installation or uninstallation test
- Importing time test
- Ensure compatibility and reliability when running programs test

8 Clinical Test

No clinical studies were conducted or necessary to establish substantial equivalence. Substantial equivalence was supported by nonclinical standalone performance testing of the device's automatic aorta segmentation and diameter measurement (see Nonclinical Performance Testing).

9 CONCLUSIONS

AVIEW Aorta Metrics has the same intended use and the principle of operation and has similar features to the predicate devices. 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.