



Coreline Soft Co., Ltd.
Hyeyi Park
Director
12, Donggyo-ro 19-gil, Mapo-gu
Seoul, 04001
South Korea

February 14, 2025

Re: K243696
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 12, 2025
Received: February 12, 2025

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.

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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. A large, faint, light blue "FDA" watermark is visible in the background behind the signature.

Jessica Lamb, Ph.D.

Assistant Director

Imaging Software Team

DHT8B: Division of Radiologic 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

Submission Number (if known)

K243696

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Coreline Soft Co., Ltd.
Applicant Address	12, Donggyo-ro 19-gil, Mapo-gu, Seoul, 04001, Republic of Korea Seoul Korea, South
Applicant Contact Telephone	+82-2-571-7321
Applicant Contact	Ms. Hyeyi Park
Applicant Contact Email	Hyeyi.park@corelinesoft.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	AVIEW CAC
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH, JAK

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233211	AVIEW CAC	QIH

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

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.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

AVIEW CAC has the same purpose and operating principle and has similar functions to the predicates device. Although there may be some differences in functions, menus and UI these differences between the prior device and the proposed device are not significant because they do not cause new or potential safety risks to users or patients and do not raise questions about safety or effectiveness. The results of the software verification and validation tests concluded that the proposed device is substantially equivalent to the predicates

device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

AVIEW CAC with software version 2.0 provides the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the legally marketed predicate device.

The software features have been modified in comparison to the predicate device to support enhanced device functionality.

The intended use, indications for use, and algorithms for the subject device remains unchanged from the predicate device. No main functions present from the predicate device have been de-scoped.

The following differences exist between the subject device and predicate devices.

- Change the installation, execution files icon
- Change the login page UI
- Change the worklist page UI
- Add a summary page
- Change the CAC page UI
- Add a minimum system requirements
- Add the function to calculate arterial age based on Agatston score

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

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.

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.