December 3, 2025

Coreline Soft Co., Ltd.
% Hyeyi Park
Director
12, Donggyo-ro 19-gil, Mapo-gu
SEOUL, 04001
SOUTH KOREA

Re: K251203
Trade/Device Name: AVIEW Lung Nodule CAD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: OEB, LLZ
Dated: October 31, 2025
Received: October 31, 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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

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)*
K251203

Device Name
AVIEW Lung Nodule CAD

Indications for Use *(Describe)*
AVIEW Lung Nodule CAD is a Computer-Aided Detection (CAD) software designed to assist radiologists in the detection of pulmonary nodules (with diameter 3-20 mm) during the review of CT examinations of the chest for asymptomatic populations. AVIEW Lung Nodule CAD provides adjunctive information to alert the radiologists to regions of interest with suspected lung nodules that may otherwise be overlooked. AVIEW Lung Nodule CAD may be used as a second reader after the radiologist has completed their initial read. The algorithm has been validated using non-contrast CT images, the majority of which were acquired on Siemens SOMATOM CT series scanners; therefore, limiting device use to use with Siemens SOMATOM CT series is 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.

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

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510(k) #: K251203

510(k) Summary

Prepared on: 2025-12-03

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 04001 Korea, South
Applicant Contact Telephone	+82-2-571-7321
Applicant Contact	Ms. Hyeyi Park
Applicant Contact Email	rat@corelinesoft.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AVIEW Lung Nodule CAD
Common Name	Lung computed tomography system, computer-aided detection
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code(s)	OEB, LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221592	AVIEW Lung Nodule CAD	OEB

Device Description Summary

21 CFR 807.92(a)(4)

The AVIEW Lung Nodule CAD is a software product that detects nodules in the lung. The lung nodule detection model was trained by Deep Convolution Neural Network (CNN) based algorithm from the chest CT image. Automatic detection of lung nodules of 3 to 20mm in chest CT images. By complying with DICOM standards, this product can be linked with the Picture Archiving and Communication System (PACS) and provides a separate user interface to provide functions such as analyzing, identifying, storing, and transmitting quantified values related to lung nodules. The CAD's results could be displayed after the user's first read, and the user could select or de-select the mark provided by the CAD. The device's performance was validated with SIEMENS' SOMATOM series manufacturing. The device is intended to be used with a cleared AVIEW platform.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

AVIEW Lung Nodule CAD is a Computer-Aided Detection (CAD) software designed to assist radiologists in the detection of pulmonary nodules (with diameter 3-20 mm) during the review of CT examinations of the chest for asymptomatic populations. AVIEW Lung Nodule CAD provides adjunctive information to alert the radiologists to regions of interest with suspected lung nodules that may otherwise be overlooked. AVIEW Lung Nodule CAD may be used as a second reader after the radiologist has completed their initial read. The algorithm has been validated using non-contrast CT images, the majority of which were acquired on Siemens SOMATOM CT series scanners; therefore, limiting device use to use with Siemens SOMATOM CT series is recommended.

Indications for Use Comparison

21 CFR 807.92(a)(5)

AVIEW Lung Nodule CAD has the same purpose and operating principle and has same functions to the predicates device. Although there may be some differences in 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 Lung Nodule CAD 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 software UI (Stylistic changes only)
• Change the Software Operation Environment

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 Lung Nodule CAD described in this submission is substantially equivalent to the predicate device.

In accordance with the guidance of 'Cybersecurity in Medical Devices: Quality System Considerations and Pre-marketing Submissions', we conducted the following tests to comply with cybersecurity requirements.
- Penetration Test

In accordance with the guidance of 'Off-The-Shelf Software Use in Medical Devices', we conducted the following tests to comply with off the shelf software requirements.
- OTS(Off-The-Shelf) Test Report

Following the guidance of 'Content of Premarket Submissions for Device Software Functions', the following tests were conducted to ensure compliance with software verification and validation requirements.
- Unit Test
- System Test
- Regression Test