September 4, 2025

Carestream Health Inc.
Jessica Deryke
Regulatory Affairs Manager
150 Verona Street
Rochester, New York 14608

Re: K251168
Trade/Device Name: Image Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 5, 2025
Received: August 5, 2025

Dear Jessica Deryke:

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,

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

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.	K251168

Please provide the device trade name(s).

Image Suite

Please provide your Indications for Use below.

Image Suite is a stand-alone radiographic imaging software designed to perform patient registration, review, report, archive, and print patient images. The software interacts with Carestream CR or DR to receive radiographic images for review, and has the ability to receive, archive, and review DICOM images from compatible third-party modalities (for example, US, MR, CT). The software can also update Carestream CR or DR device firmware and monitor device calibration. The software serves as a web server to support web clients for image viewing. Image Suite is intended for use by radiologists and trained healthcare professionals. The software presents images to medical professionals in a convenient digital medium so they can make diagnostic and/or therapeutic decisions.
This excludes mammography applications and Tablet Viewer applications in the United States.

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

510(k) Owner Name: Carestream Health, Inc.
510(k) Owner Address: 150 Verona Street
Rochester, NY, 14608

510(k) Owner Phone: 585-627-6505
510(k) Owner Fax: 585-627-8802

Contact Person & Info: Jessica DeRyke
Regulatory Affairs Manager
Jessica.deryke@carestream.com
585-489-7627

Date Summary Prepared: September 3, 2025

Device Classification Information:

Predicate
510(k) Submitter: Carestream Health, Inc.
Trade Name: Tablet Viewer Software for Image Suite
Device: System, Image Processing, Radiological
Regulation Description: Picture Archiving and Communication System
Review Panel: Radiology
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Device Class: II

Subject Device
510(k) Submitter: Carestream Health, Inc.
Trade Name: Image Suite
Device: System, Image Processing, Radiological
Regulation Description: Medical Image Management and Processing System
Review Panel: Radiology
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Device Class: II

Device Description:

Image Suite software is a Picture Archiving and Communication System (PACS) that allows patient registration, image acquisition, processing, reviewing, reporting, archiving and printing of radiographic images from compatible Carestream image acquisition devices, such as digital radiography (DR) detectors or computed radiography (CR) systems. In addition to being designed to function with images acquired from Carestream compatible devices, Image Suite can receive DICOM images from compatible third-party modalities (for example, Ultrasound, MRI, CT). Third party images may be viewed and archived by Image Suite, but no changes to the raw image from the third-party device are possible.

This Image Suite submission adds features that are commercially available on other Carestream products. Image Suite utilizes the same image processing software (Eclipse) as the Carestream CR and DR devices that the features being detailed in this submission were previously cleared on. These features include:

- Companion Imaging
    - Tube & PICC Line /High Detail Visualization/Skeletal Enhancement (commercially available option in x-ray systems under K120062)
    - Pneumothorax visualization (does not detect the pneumothorax) (commercially available option in x-ray systems K120062)
    - Bone Suppression (previously cleared in K133442)
- Multiple Looks (subset of the looks provided in the commercially available x-ray systems)
- Smart Grid (cleared under K163157).

This submission will also address cumulative changes made since the last 510(k) submission K140271. Over time minor changes have been made to the Image Suite product that have not impacted safety or effectiveness of the product.

Indication for Use:

Image Suite is a stand-alone radiographic imaging software designed to perform patient registration, review, report, archive, and print patient images. The software interacts with Carestream CR or DR to receive radiographic images for review, and has the ability to receive, archive, and review DICOM images from compatible third-party modalities (for example, US, MR, CT). The software can also update Carestream CR or DR device firmware and monitor device calibration. The software serves as a web server to support web clients for image viewing. Image Suite is intended for use by radiologists and trained healthcare professionals. The software presents images to medical professionals in a convenient digital medium so they can make diagnostic and/or therapeutic decisions.

This excludes mammography applications and Tablet Viewer applications in the United States

Comparison of Technological Characteristics:

A substantial equivalence table (Table 1) provides the similarities and differences between the modified and predicate devices.

Table 1: Substantial Equivalence Table

	Predicate: **Image Suite (with Tablet Viewer Software)**	Subject Device: **Image Suite**	New Feature to Image Suite
510(k) Number	K140271	K251186	N/A
Indications for Use	CARESTREAM Image Suite is an image management system whose intended use is to receive, process, review, display, print and archive images and data from all imaging modalities. Tablet Viewer Software for Image Suite is used for patient management by clinicians in order to access and display patient data, medical reports, and medical images for diagnosis from different modalities including CR, DR, CT, MR, and US. Tablet Viewer Software for Image Suite provides wireless and portable access to medical images for remote reading or referral purposes from web browsers including usage with validated mobile devices. This device is not intended to replace the full Mini- PACS and should be	Image Suite is a stand-alone radiographic imaging software designed to perform patient registration, review, report, archive, and print patient images. The software interacts with Carestream CR or DR to receive radiographic images for review, and has the ability to receive, archive, and review DICOM images from compatible third-party modalities (for example, US, MR, CT). The software can also update Carestream CR or DR device firmware and monitor device calibration. The software serves as a web server to support web clients for image viewing. Image Suite is intended for use by radiologists and trained healthcare professionals. The software presents images to medical professionals in a convenient digital medium so they can make diagnostic and/or therapeutic decisions.	N/A

	used only when there is no access to the full Mini-PACS Web Viewer. This excludes mammography applications in the United States.	This excludes mammography applications and Tablet Viewer applications in the United States	
Image Processing Software	Eclipse	Eclipse II	No
Display	Multi- Monitor Display or iPad 2	Multi- Monitor Display	No
Operating System	Windows or iOS	Same	No
Browser	Internet Explorer or Safari	Same	No
DICOM support	Yes	Same	No
Modalities	Carestream Health: CR and DR modalities Third party: CR, DR, CT, MR, and US modalities	Same	No
Measurement Capabilities	Yes	Same	No
Display Measures	Yes	Same	No
2D Display	Yes	Same	No
Cine Mode	Yes	Same	No
Zoom Images	Yes	Same	No
Rotate/Flip Images	Yes	Same	No
Window Level Adjustment	Yes	Same	No
Layout adjustment	Yes	Same	No
Lossy vs. Lossless	Yes	Same	No
Tube & PICC Line/ High Detail Visualization (Companion View)	No	New Image Suite Feature Cleared in K120062	Yes
Pneumothorax (Companion View)	No	New Image Suite Feature Cleared in K120062	Yes

Bone Suppression (Companion View)	No	New Image Suite Feature Cleared in K133442	Yes
X-Factor	No	New Image Suite Feature	Yes
Multiple Looks	One look available	Previously available on Image Suite there are now Four looks available	Yes
Smart Grid	No	New Image Suite Feature Cleared in K163157	Yes

Discussion of Nonclinical Testing

Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Software testing was conducted under simulated use conditions. Predefined acceptance criteria were met and demonstrated that the device is as safe and as effective as the predicate devices.

Conclusion of Substantial Equivalence:

The comparison of the predicate and subject devices demonstrates that they are substantially equivalent in terms of their intended use, technological characteristics, and performance outcomes. Both devices fulfill the same primary functions and achieve comparable results, ensuring their safety and efficacy within their defined applications. Any differences in design or components are non-significant and do not affect the overall operation or intended purpose of the devices. Therefore, these distinctions do not raise new questions regarding their safety or effectiveness, supporting the assertion of substantial equivalence.