



March 13, 2026

Canon Medical Systems Corporation
% Yoshiaki Cook
Sr. Manager, Regulatory Affairs
Canon Medical Systems, USA
2441 Michelle Dr.
TUSTIN, CA 92780

Re: K260078

Trade/Device Name: Aquilion Serve SP (TSX-307B) V2.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: January 9, 2026
Received: January 12, 2026

Dear Yoshiaki Cook:

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,

A large, light blue 'FDA' watermark is visible in the background. Overlaid on it is a handwritten signature in black ink that reads 'Lu Jiang'.

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

510(k) Number (if known)
K260078

Device Name
Aquilion Serve SP (TSX-307B) V2.0

Indications for Use (Describe)

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head.

The Aquilion Serve SP has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

AiCE (Advanced Intelligent Clear-IQ Engine) is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, cardiac, extremities, head and inner ear applications.

PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac, abdomen, pelvis, and lung applications, in comparison to FBP and hybrid iterative reconstruction.

CLEAR Motion is a Deep Learning Reconstruction (DLR) method designed to reduce motion artifacts. A Deep Convolutional Neural Network (DCNN) is used to estimate the patient's motion. This information is used in the reconstruction process to obtain lung images with less motion artifacts.

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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CANON MEDICAL SYSTEMS USA, INC.

*Made For life***510(k) SUMMARY****1. SUBMITTER'S NAME:**

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2. ESTABLISHMENT REGISTRATION:

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON:

Yoshiaki Cook
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Canon Medical Systems USA, Inc
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(657) 270-5595

4. DATE PREPARED:

January 09, 2026

5. TRADE NAME(S):

Aquilion Serve SP (TSX-307B) V2.0

6. COMMON NAME:

System, X-ray, Computed Tomography System

7. DEVICE CLASSIFICATION:

Classification Name: Computed Tomography X-ray system
Regulation Number: 21 CFR §892.1750
Regulatory Class: Class II

8. PRODUCT CODE:

JAK

9. PERFORMANCE STANDARD:

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

10. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Aquilion Serve SP V1.3	Canon Medical Systems USA	21 CFR §892.1750	Computed Tomography System	JAK	K233334	12/06/2023

11. REASON FOR SUBMISSION:

Modification of a cleared device

12. DEVICE DESCRIPTION:

The Aquilion Serve SP (TSX-307B) V2.0 This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, pancreas, etc.

The Aquilion Serve SP has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

This system is based upon the technology and materials of previously marketed Canon CT Systems.

13. INDICATIONS FOR USE:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head.

The Aquilion Serve SP has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

AiCE (Advanced Intelligent Clear - IQ Engine) is a noise reduction algorithm that improves image quality and reduces image noise by employing Deep Convolutional Neural Network methods for abdomen, pelvis, lung, cardiac, extremities, head and inner ear applications.

PIQE is a Deep Learning Reconstruction method designed to enhance spatial resolution. By incorporating noise reduction into the Deep Convolutional Neural Network (DCNN), it is possible to achieve both spatial resolution improvement and noise reduction for cardiac, abdomen, pelvis, and lung applications, in comparison to FBP and hybrid iterative reconstruction.

CLEAR Motion is a Deep Learning Reconstruction (DLR) method designed to reduce motion artifacts. A Deep Convolutional Neural Network (DCNN) is used to estimate the patient's motion. This information is used in the reconstruction process to obtain lung images with less motion artifacts.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE (TSX-308A/TSX-306A) V2.0** is substantially equivalent to Aquilion Serve SP (TSX-307B/1) V1.3, which received premarket clearance under K233334, and is currently marketed by Canon Medical Systems USA.

The subject and predicate devices are the same with the only differences being: Implementation of the PIQE Reconstruction System for Cardiac, Body, and Lung anatomical areas and implementation of the CLEAR Motion reconstruction system for the Body and Lung anatomical areas.

A comparison of the relevant technological characteristics between the subject and the predicate device is included below.

	Subject Device	Predicate Device
Device Name, Model Number	Aquilion ONE (TSX-308A/TSX-306A) V2.0	Aquilion Serve SP (TSX-307B/1) V1.3
510(k) Number	This submission	K233334
CLEAR Motion Reconstruction System	Body and Lung scan reconstruction capabilities	N/A – feature not available, but previously cleared under K242403.
PIQE Reconstruction System	Cardiac, Body, and Lung scan reconstruction capabilities	N/A – feature not available, but previously cleared under K242403.

15. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the following standards IEC60601-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC81001-5-1, IEC62366-1, NEMA XR-25, NEMA XR-26, NEMA XR-29 and NEMA NU-2. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

16. TESTING

Risk analysis and verification/validation activities conducted through bench testing demonstrate that the established specifications for the device have been met.

16a. CLEAR Motion for Body and Lung

CLEAR Motion Lung is an AI-based image reconstruction algorithm designed to reduce cardiac-induced motion artifacts in lung CT imaging. It utilizes a deep convolutional neural network (DCNN) trained to produce motion-compensated images. The network was trained offline using 3,400 partial image pairs derived from 37 clinical lung CT cases, covering a range of doses, field-of-view sizes, and helical pitches. The AI model adapts to variations in noise texture and anatomical motion patterns, with the final output demonstrating improved clarity of lung and heart structures, with suppression of motion blur and enhanced diagnostic quality. The algorithm was unchanged by its implementation into the subject device.

Performance Testing - CLEAR Motion Lung Dynamic Phantom Evaluation

In this evaluation, the algorithm was applied to a dynamic thoracic phantom simulating pulmonary vessel motion. This test compared CLEAR Motion reconstructions to standard reconstructions under controlled scan conditions (helical mode, 120 kV, 0.5 mm × 80 collimation, 0.5 sec/rot, 300 mA), with results confirming that CLEAR Motion significantly reduced motion artifacts without introducing distortion or loss of anatomical structures.

Performance Testing – CLEAR Motion Lung Non-Dynamic Phantom Evaluation

The CLEAR Motion algorithm was evaluated using a non-dynamic water phantom to assess its impact on CT number accuracy across a range of dose levels, to confirm that CLEAR Motion reconstruction does not introduce significant artifacts and maintains CT number consistency within ± 5 HU compared to standard reconstructions. The evaluation included multiple reconstruction methods —FBP, AIDR3D, AiCE, and PIQE—across lung and soft tissue. CLEAR Motion consistently met the acceptance criteria, showing minimal CT number variation and no visual artifacts, demonstrating its enhancement of image quality by compensating for motion during reconstruction.

Performance Testing – CLEAR Motion IQ Report Phantom Study

This study evaluated the performance of the CLEAR Motion algorithm to correct for motion during image acquisition, improving spatial fidelity and diagnostic clarity, using a dynamic thoracic phantom to simulate respiratory motion. The objective was to assess the algorithm's ability to reduce motion artifacts in lung CT imaging across various anatomical structures including pulmonary vessels, airways, and the diaphragm. Scans were performed under multiple pitch factors and reconstruction methods (AIDR3D and AiCE), both with and without CLEAR Motion applied. The results demonstrated that CLEAR Motion consistently reduced motion artifacts across all tested conditions, supporting the safe and effective use of CLEAR Motion for thoracic imaging.

Performance Testing – CLEAR Motion Clinical Image Quality Evaluation

A clinical evaluation of the CLEAR Motion algorithm was conducted using lung CT datasets acquired on the TSX-307B system with iSeries V2.0 SP0000 software, in order to assess the capability of CLEAR Motion to improve image quality by reducing motion artifacts without introducing distortion or loss of anatomical structures. The evaluation included five representative cases with varying scan parameters and dose levels (1.1–5.1 mGy), reconstructed using AIDR3D Lung and AiCE Lung methods, both with and without CLEAR Motion. CLEAR Motion demonstrated consistent visual improvement in motion artifacts, particularly around the heart wall and liver dome. Additionally, performance remained stable across different display field-of-view (dFOV) settings, demonstrating the performance CLEAR Motion for improving diagnostic image quality in lung CT imaging.

Performance Testing – CLEAR Motion Justification for the Use of DLR Algorithm, CLEAR Motion Lung

This presentation provides the technical basis for the deployment of the CLEAR Motion algorithm on the Aquilion Serve SP (TSX-307B) CT system, confirming its compatibility and performance equivalence with prior implementations on Canon Aquilion ONE / INSIGHT systems. The evaluation included phantom and clinical image comparisons across multiple reconstruction methods (FBP, AIDR3D, AiCE) and scan conditions. Quantitative analysis showed consistent CT value accuracy with and without CLEAR Motion, and visual assessments

demonstrated improved image clarity in dynamic and clinical scenarios, confirming that CLEAR Motion functions as intended when implemented on the Serve SP platform.

16b. PIQE for Cardiac, Body, and Lung

PIQE is an AI-based image reconstruction algorithm which utilizes a DCNN designed to improve CT image quality by reducing noise and enhancing spatial resolution across cardiac, body, and lung applications.

The retraining process used high-resolution AiCE images from an ultra-high-resolution CT system (Aquilion Precision) as targets and simulated normal-resolution AIDR3D images as inputs, incorporating multiple dose levels and display field-of-view variations to improve robustness. For cardiac imaging, 18 anonymized clinical cases (13 UHR-CT and 5 NR-CT) were included, generating over 13,000 training pairs, while body imaging used 28 cases spanning thoracic to pelvic regions, producing 1,845 large training pairs. Data augmentation techniques were applied to enhance feature diversity, and 5% of samples were reserved for validation to prevent overfitting. This approach enabled the algorithm to learn noise reduction and resolution enhancement.

Performance Testing – PIQE IQ Metrics Evaluation

This study evaluated the image quality performance of PIQE with the subject device. PIQE was benchmarked against Filtered Backprojection (FBP) and AIDR Enhanced (AIDR3D) across multiple clinical and phantom-based metrics, including contrast-to-noise ratio (CNR), CT number accuracy, uniformity, modulation transfer function (MTF), noise power spectra (NPS), and low contrast detectability (LCD). PIQE demonstrated superior or equivalent performance in all categories, with notable improvements in noise reduction, spatial resolution, and low contrast detectability, while avoiding overenhancement artifacts common in traditional methods, resulting in cleaner images and improved signal-to-noise ratios. These findings support the safe and effective use of PIQE for clinical CT imaging.

Performance Testing – Justification for the Use of the DLR Algorithm (PIQE)

This presentation provides the technical basis for the use of the PIQE algorithm on the Aquilion Serve SP (TSX-307B) CT system, based on the similarity of imaging chains between the subject device and the Aquilion ONE / PRISM systems in which PIQE was previously implemented, including equivalent noise characteristics and image quality performance. Comparative evaluations using phantom and clinical data confirmed consistent CT value accuracy and noise performance across both platforms, demonstrating that PIQE remains safe and effective for its intended use when implemented on the Serve SP platform.

All prespecified acceptance criteria for performance were passed, demonstrating the substantial equivalence by the improved features relative to the existing features upon which they were predicated.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, “Content of Premarket Submissions for Device Software Functions” issued on June 14, 2023, is included in this submission. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation, per the FDA guidance document “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”, issued on June 27, 2025, was included in this submission.

17. CONCLUSION

The **Aquilion Serve SP (TSX-307B) V2.0** performs in a manner similar to and is intended for the same use as the predicate device, as indicated in product labeling. Based upon this information, conformance to standards, successful completion of software validation, application of risk management and design controls and the performance data presented in this submission it is concluded that the subject device has demonstrated substantial equivalence to the predicate device and is as safe and effective for its intended use.