December 6, 2023

Canon Medical Systems Corporation
% Orlando Tadeo
Sr. Manager, Regulatory Affairs
Canon Medical Systems, USA
2441 Michelle Drive
TUSTIN, CA 92780

Re: K233334
Trade/Device Name: Aquilion Serve SP (TSX-307B/1) V1.3
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: September 29, 2023
Received: November 13, 2023

Dear Mr. Tadeo:

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.

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
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OHT8: Office of Radiological Health
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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.

Submission Number *(if known)*

K233334

Device Name

Aquilion Serve SP (TSX-307B/1) V1.3

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.

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.

510(k) SUMMARY **K233334**

1. SUBMITTER'S NAME:

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Canon Medical Systems Corporation
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Otawara-Shi, Tochigi-ken, Japan 324-8550

2. ESTABLISHMENT REGISTRATION:

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON:

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4. DATE PREPARED:

September 29, 2023

5. TRADE NAME(S):

Aquilion Serve SP (TSX-307B/1) V1.3

6. COMMON NAME:

Computed Tomography X-ray System

7. DEVICE CLASSIFICATION:

a) Classification Name: Computed Tomography X-ray system
b) Regulation Number: 21 CFR §892.1750
c) 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 (TSX-307A/1) V1.3 *Primary Predicate*	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K231281	September 19, 2023
Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i *Reference Predicate*	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K192832	February 21, 2020

11. REASON FOR SUBMISSION:

Modification of a cleared medical device

12. DEVICE DESCRIPTION:

Aquilion Serve SP (TSX-307B/1) V1.3 is a whole body multi-slice helical CT scanner, consisting of a gantry, couch and a console used for data processing and display. This device captures cross sectional volume data sets used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician. This system is based upon the technology and materials of previously marketed Canon CT systems.

Aquilion Serve SP (TSX-307B/1) V1.3 is equipped with SilverBeam Filter which is a beam shaping filter that leverages the photon-attenuating properties of silver to selectively remove low energy photons from a polychromatic X-ray beam, leaving an energy spectrum optimized for high contrast CT applications.

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.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Serve SP (TSX-307B/1) V1.3** is substantially equivalent to **Aquilion Serve (TSX-307A/1) V1.3**, which received premarket clearance under K231281, and is marketed by Canon Medical Systems USA. The intended use of the **Aquilion Serve SP** is the same as that of the predicate device. The **Aquilion Serve SP (TSX-307B/1) V1.3** includes implementation of a 7.5 MHU X-ray tube and the increased X-ray generator output which are identical to the components that received 510(k) clearance as part of the Aquilion Prime SP (TSX-303B/8), K1912832. A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	Primary Predicate Device	Reference Predicate Device
Device Name, Model Number	**Aquilion Serve SP (TSX-307B/1) V1.3**	**Aquilion Serve (TSX-307A/1) V1.3**	**Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i**
510(k) Number	**This submission**	**K231281**	**K192832**
X-ray generation			
Channel-direction (fan) angle	49.2°	49.2°	49.2°
Rated output	Max.72 kW (with Option installed)	Max. 50.4 kW	Max.72 kW (with Option installed)
X-ray tube voltage	80/100/120/135 kV	80/100/120/135 kV	80/100/120/135 kV
X-ray tube current*	10 - 600 mA* 10 - 500 mA (* with Option installed)	10 - 420 mA	10 - 600 mA* 10 - 500 mA (* with Option installed)
X-ray tube heat capacity	7.5 MHU	5.0 MHU	7.5 MHU
X-ray tube cooling rate	Max. 1,386 kHU/min (16.5 kW) Actual 1,008 kHU/min (12.0 kW)	Max. 864 kHU/min	Max. 1,386 kHU/min (16.5 kW) Actual 1,008 kHU/min (12.0 kW)
Focal spots sizes – IEC 60336: 2005, nominal:	Small: 0.9 mm x 0.8 mm Large: 1.6 mm x 1.4 mm	Small: 0.9 mm x 0.7 mm Large: 1.4 mm x 1.4 mm	Small: 0.9 mm x 0.8 mm Large: 1.6 mm x 1.4 mm
X-ray tube inherent filtration	1.0 mm Al equivalent or more	1.0 mm Al equivalent or more	1.0 mm Al equivalent or more
X-ray generator (HFG)	Model: CXXG-012A	Model: CXXG-015A	Model: CXXG-012A

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, IEC60601-1-9, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366-1, NEMA XR-25, NEMA XR-26 and NEMA XR-29. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

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

16. TESTING:

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

Performance Testing - Bench

Objective Image Quality Evaluation

CT image quality metrics were performed, utilizing phantoms, to assess Contrast-to-Noise Ratios (CNR), CT Number Accuracy, Uniformity, Slice Sensitivity Profile (SSP), Modulation Transfer Function (MTF)-Wire, Modulation Transfer Function (MTF)-Edge, Standard Deviation of Noise (SD), Noise Power Spectra (NPS), Low Contrast Detectability (LCD) and Pediatric phantom/protocol. It was concluded that the performance of TSX-307B (Serve SP) was improved and/or substantially equivalent to the predicate device as demonstrated by the results of the testing.

Dose Reduction Mode (DR-Mode) - SilverBeam

A study was conducted to confirm that Dose Reduction mode (DR-Mode), which uses the SilverBeam Filter, is able to realize dose reduction compared to normal scan mode. Utilizing 160mm and 320 mm dosimetry phantoms, $CTDI_{100}$ and CTDIw values for Head and Body modes were compared between normal scan mode and DR-Mode. Results of the study demonstrated that DR-Mode (with SilverBeam Filter) is able to achieve dose reduction in both Head and Body modes compared to normal scan mode.

A summary of the risk analysis and verification/validation testing conducted through bench testing is included in this submission which demonstrates that the requirements for the system have been met.

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 cybersecurity premarket guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices " issued on October 2, 2014, is also included as part of this submission.

17. CONCLUSION:

The **Aquilion Serve SP (TSX-307B/1) V1.3** 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 safe and effective for its intended use.