March 3, 2023

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

Re: K222819
Trade/Device Name: Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: February 1, 2023
Received: February 2, 2023

Dear Orlando 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222819

Device Name

Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i

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 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.

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510(k) SUMMARY

1. SUBMITTER'S NAME:

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2. ESTABLISHMENT REGISTRATION:

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON:

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Canon Medical Systems USA, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

4. DATE PREPARED:

September 16, 2022

5. TRADE NAME(S):

Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i

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
Primary Predicate: Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K201836	01/12/2021
Reference Predicate: Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K192832	02/21/2020

11. REASON FOR SUBMISSION:

New medical device

12. DEVICE DESCRIPTION:

Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i (Advanced intelligent Clear-IQ Engine-integrated) 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.

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 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 (TSX-307A/1) V1.2 with AiCE-i** is substantially equivalent to **Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i**, which received premarket clearance under K201836, and is marketed by Canon Medical Systems USA. The intended use of the **Aquilion Serve** is the same as that of the predicate device.

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

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i**	**Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i**	
510(k) Number	**This submission**	**K201836**	
Scan modes	Conventional scan (Axial Scan*) Volume, Dynamic volume scan Helical scan	Conventional scan (S&S, S&V) Volume, Dynamic volume scan Helical scan	*: S&V is not supported S&S is called "Axial Scan"

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i**	**Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i**	
510(k) Number	**This submission**	**K201836**	
Positioning Scan	Positioning: Single Dual 3D Landmark Scan	Scanoscopy: Scano Dual Scano	
3D Landmark Scan	Available	Not Available	
Anatomical Landmark Detection	Available	Not Available	
Scan planning assist function*	Available	Not Available	*: If 3D Landmark Scan is set in a scan protocol.
Scan slice thickness	[Conventional scan (Axial scan)] 4-row scan: 0.5, 1, 2, 3, 4, 5, 8 mm 1-row scan: 1 mm [Volume, Dynamic volume scan] (80-row scan*: 0.5 mm) 40-row scan: 0.5 mm [Helical scan] (80-row scan*: 0.5 mm) 40-row scan: 0.5 mm and 1 mm 20-row scan: 0.5 mm 4-row scan: 0.5 mm [3D Landmark Scan] 40-row scan: 1.0 mm	[Conventional scan (S&S, S&V)] 4-row scan: 0.5, 1, 2, 3, 4, 5, 8, 10 mm 1-row scan: 1 mm [Volume, Dynamic volume scan] (80-row scan*: 0.5 mm) 40-row scan: 0.5 mm and 1 mm 4-row scan: 8 mm and 10 mm [Helical scan] (80-row scan*: 0.5 mm) 40-row scan: 0.5 mm and 1 mm 20-row scan: 0.5 mm and 1 mm 4-row scan: 0.5 mm	*: Option
Image reconstruction time	Up to 30 images/s with AIDR 3D (0.033 s/image) Up to 50 images/s with AIDR 3D (0.02 s/image)[*1] Up to 70 images/s with AIDR 3D (0.014 s/image)[*2] Up to 100 images/s with AIDR 3D (0.01 s/image)[*3] (Depending on the scan and reconstruction conditions)	Up to 20 images/s with AIDR 3D (0.05 s/image) Up to 50 images/s with AIDR 3D (0.02 s/image) [*2] (Depending on the scan and reconstruction conditions)	*1: When the Fast scan kit (CGS-041A) is installed. *2: Option When the Fast Image Reconstruction kit (CCFR-010A) is installed. *3: When the Fast Image Reconstruction kit (CCFR-010A) and the Fast scan kit (CGS-041A) are installed.
Flex e-Tilt	Available	Not Available	

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i**	**Aquilion Lightning (TSX-036A/7) V10.2 with AiCE-i**	
510(k) Number	**This submission**	**K201836**	
Gantry opening diameter (aperture)	800 mm in diameter	780 mm in diameter	
Wedge filter types	Three (3) types ・Small ・Large ・SilverBeam Filter*	Two (2) types ・Small ・Large	*Previously cleared under K213504 (TSX-306A)
Gantry internal cameras	Available	Not Available	Two cameras mounted inside the system at a 90-degree phase difference.
Reconstruction functions	Identified as anatomical regions*	Identified as numbered functions	*Previously cleared under K213504 (TSX-306A)
Noise reduction processing	Adaptive Iterative Dose Reduction 3D (AIDR 3D) AIDR 3D Enhanced Advanced Intelligent Clear-IQ Engine (AiCE)	Adaptive Iterative Dose Reduction 3D (AIDR 3D) AIDR 3D Enhanced Advanced Intelligent Clear-IQ Engine (AiCE) Quantum Denoising Software (QDS)	
NewUX Console*	Available	Not Available	*Previously cleared under K213504 (TSX-306A)
Display monitor	27 inch (3840 x 2160)	19 inch (1280 x 1024)	
User Input	Keyboard and Control Pad (Performs scan operation and controls voice messages)	Scan Keyboard	
Data processor	CPU : 64-bit Memory size: 64 Gbyte or more	CPU : 64-bit Memory size: 32 Gbyte or more	
Window width/level	Controlled and continuously variable using the mouse	Controlled and continuously variable using a speed-sensitive rotary encoder	
Preset windows	1/image	3/image	
Window types	Linear only	Linear and non-linear (6 user-programmable), and double windows	
ROI shape available	Point, Circular	Point, square, free-form, circular, polygon	

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, 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 IQ Performance Comparison

An image quality metric evaluation comparing performance of the TSX-307A (Aquilion Serve) system relative to the predicate device was conducted. In order to compare the image quality between these two systems, the following image quality performance tests were conducted. It was concluded that the subject device demonstrated equivalent or improved performance, compared to the predicate device, as demonstrated by the results of the above testing.

1. Contrast-to-Noise Ratios (CNR)
2. CT Number Accuracy
3. Uniformity
4. Slice Sensitivity Profile (SSP)
5. Modulation Transfer Function (MTF)-Wire
6. Standard Deviation of Noise (SD)
7. Noise Power Spectra (NPS)
8. Low Contrast Detectability (LCD)

Image Quality Metric Evaluation

An image quality metric evaluation of Aquilion Serve (TSX-307A/1) V1.2 reconstructed with AiCE, for the available Body, Body Sharp, Lung, Bone, Inner ear, Brain LCD, Brain CTA and Cardiac modes was conducted and equivalent or improved image quality performance relative to FBP and AIDR 3D was demonstrated. The following image quality performance tests were conducted: 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), Pediatric.

AiCE Reconstruction for Lung Cancer Screening Image Quality Metric Evaluation

The performance of the subject device (Aquilion Serve with AiCE) was compared to the results for the Aquilion ONE / GENESIS Edition with the AAPM lung cancer screening protocol for both a small and a larger sized phantom. Please note the AAPM protocol

does not use a fixed mA, but rather an automatic exposure setting of 20HU. Therefore, the dose for the predicate device was determined by first establishing the AEC-predicated dose for each phantom and then scanning with a fixed technique on the GENESIS based on the result. The nearest fixed technique on the Serve was then scanned. All results were reconstructed with AIDR (FC18 and FC52) as prescribed by the AAPM protocol and were also reconstructed with AiCE DLR Body Sharp and AiCE Lung and FBP FC18.

In order to compare the image quality between AiCE DLR on the Aquilion Serve and Aquilion ONE / GENESIS Edition with AIDR (AAPM protocol), the following image quality performance tests were conducted:

1. Contrast-to-Noise Ratios (CNR)
2. CT Number Accuracy
3. Uniformity
4. Slice Sensitivity Profile (SSP)
5. Modulation Transfer Function (MTF)-Edge
6. Standard Deviation of Noise (SD)
7. Noise Power Spectra (NPS)

It was concluded that the subject device demonstrated equivalent or improved performance as demonstrated by the results of the above testing.

Automatic Scan Planning

Volunteer assessment demonstrated that couch movement appropriately positioned volunteers to the selected anatomical region.

Flex e-Tilt

Image comparison studies were conducted between Flex e-Tilt reconstructed images with the Aquilion Serve versus conventional tilt and MPR (oblique) images utilizing the predicate device, Aquilion Lightning. It was determined that the images were equivalent and there were no significant differences observed.

Noise Texture

An analysis of the NPS and kurtosis values for FBP, FIRST and AiCE was conducted and the results of the study support the following claims, more natural noise texture compared to FIRST, noise texture as natural as filtered backprojection, and noise texture distinct from MBIR.

Quantitative Spatial Resolution

A comparison study was conducted, utilizing phantoms, in order to support a quantitative spatial resolution improvement claim of twice the high contrast spatial resolution for AiCE Body at 10% MTF and a 4.1 lp/cm increase in high contrast spatial resolution for AiCE Cardiac at 10% MTF as compared to AIDR reconstruction.

Quantitative Body LCD and Noise Improvement and Dose Reduction

A phantom study was conducted using the MITA - FDA LCD Body phantom and the results demonstrated improved low contrast detectability at the same dose for AiCE body compared to AIDR, noise reduction with AiCE at the same dose for body compared to AIDR and dose reduction for AiCE Abdomen relative to FBP.

3D Scano Water Equivalence

A comparison phantom study was conducted utilizing a 24cm and 32cm water phantom to demonstrate that both 3D Scano and dual scano produced 24cm and 32cm water equivalent diameters with less than 5% mean absolute error.

Low Contrast Detectability Evaluation

A phantom study was conducted in order to support claims of low-contrast detectability of 8.8 mGy (0.3%/3 mm) of AIDR3D, and 15.9mGy (0.3% / 2mm) and 8.1mGy (0.3% / 3mm) of AiCE, respectively.

Performance Testing – Clinical Images

Representative body, cardiac, chest, head, and extremity diagnostic images, reviewed by an American Board-Certified Radiologist, were obtained using the subject device and it was confirmed that the reconstructed images using the subject device were of diagnostic quality.

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

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is included in this submission. This documentation includes justification for the Moderate Level of Concern determination as well as testing which demonstrates that the verification and validation requirements for the modifications described above have been met.

A Software Information Checklist is included at the conclusion of this Executive Summary.

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 (TSX-307A/1) V1.2 with AiCE** 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.