September 19, 2023

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

Re: K231281
Trade/Device Name: Aquilion Serve (TSX-307A/1) V1.3
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 2, 2023
Received: May 3, 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 Radiological 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)*
K231281

Device Name

Aquilion Serve (TSX-307A/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 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.

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

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510(k) SUMMARY

1. SUBMITTER'S NAME:

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2. ESTABLISHMENT REGISTRATION:

9614698

3. OFFICIAL CORRESPONDENT/CONTACT PERSON:

Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
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2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

4. DATE PREPARED:

April 28, 2023

5. TRADE NAME(S):

Aquilion Serve (TSX-307A/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) V1.2 with AiCE-i	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K222819	March 3, 2023

11. REASON FOR SUBMISSION:

Modification of a cleared medical device

12. DEVICE DESCRIPTION:

Aquilion Serve (TSX-307A/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.

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) V1.3** is substantially equivalent to **Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i**, which received premarket clearance under K222819, and is marketed by Canon Medical Systems USA. The intended use of the **Aquilion Serve** is the same as that of the predicate device. The **Aquilion Serve (TSX-307A/1) V1.3** includes implementation of a Dynamic scan mode, Exposure reduction mode, Dual Energy scanning and Extended field of view. 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) V1.3**	**Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i**	
510(k) Number	**This submission**	**K222819**	
Scan modes	Conventional scan (Axial Scan) Volume, Dynamic volume scan Dynamic scan Helical scan	Conventional scan (Axial Scan) Volume, Dynamic volume scan Helical scan	- Dynamic scan is a continuous scanning mode for a target region.
Scan slice thickness	[Volume, Dynamic volume, Dynamic scan] (80-row scan[*1]: 0.5 mm) 40-row scan: 0.5 mm 8-row scan: 0.5 mm[*2] 4-row scan: 0.5, 1 and 2 mm[*2]	[Volume, Dynamic volume scan] (80-row scan[*1]: 0.5 mm) 40-row scan: 0.5 mm	[*1]: Option Dynamic volume CT upgrade kit (CGS-55A) is mandatory. [*2]: For Dynamic scan only

	Subject Device	Predicate Device	Comment
Device Name, Model Number	**Aquilion Serve (TSX-307A/1) V1.3**	**Aquilion Serve (TSX-307A/1) V1.2 with AiCE-i**	
510(k) Number	**This submission**	**K222819**	
Exposure (Dose) reduction mode	Standard o Wedge: SilverBeam Filter	N/A	Previously cleared under K213504
Dual energy system	Option	N/A	Previously cleared under K132813
Extended field of view	Option	N/A	Reconstruction field up to 800 mm for data acquired with an FOV of 500 mm, becomes available.

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

SilverBeam Image Quality Evaluation

CT image quality assessments were performed, utilizing phantoms, to evaluate the performance of SilverBeam with AiCE with regard to Standard Deviation of Noise (SD) and visual inspection for artifacts/distortion/obscurity of structures. 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.

SilverBeam Dose Reduction

A phantom study was conducted which compared dose in Head/Body modes between normal scan mode and in DR-mode (with SilverBeam Filter) and it was determined that DR-mode resulted in dose reduction.

Workflow Evaluation

A user evaluation was conducted to assess the workflow of non-contrast chest and chest-to-abdomen scans as it relates to the typical operational steps of CT examinations compared with utilizing Anatomical Landmark Detection (ALD). It was determined that there was a reduction in the number of clicks and more consistent scan planning with ALD and the results demonstrated a 24% reduction in scan planning time.

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 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.

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) V1.3** 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.