



February 21, 2020

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

Re: K192832

Trade/Device Name: Aquilion Prime SP (TSX-303B8) V10.2 with AiCE-i  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: Class II  
Product Code: JAK  
Dated: January 17, 2020  
Received: January 21, 2020

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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K192832

Device Name

Aquilion Prime SP (TSX-303B/8) V10.2 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 Prime 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.

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

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**2. OFFICIAL CORRESPONDENT:**

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**3. ESTABLISHMENT REGISTRATION:**

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(714) 669-7459

**5. Date Prepared:**

September 30, 2019

**6. TRADE NAME(S):**

Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i

**7. COMMON NAME:**

System, X-ray, Computed Tomography

**8. DEVICE CLASSIFICATION:**

- a) Classification Name: Computed Tomography X-ray system
- b) Regulation Number: 892.1750
- c) Regulatory Class: Class II

**9. PRODUCT CODE / DESCRIPTION:**

JAK – System, Computed Tomography

**10. PREDICATE DEVICE:**

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Aquilion Prime SP, TSX-303B/1, v8.4 (Primary Predicate Device)	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K172188	October 6, 2017
Aquilion ONE (TSX-305A/6) V8.9 with AiCE (Reference Device)	Canon Medical Systems, USA	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K183046	June 12, 2019

**11. REASON FOR SUBMISSION:**

Modification of a cleared device

**12. DEVICE DESCRIPTION:**

The **Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i** is a 40-row CT System that is intended to acquire and display cross-sectional volumes of the whole body, including the head. An optional Dynamic Volume CT Upgrade Kit can be installed in order to expand the active detector rows to 80. This system is based upon the technology and materials of previously marketed Canon CT systems. In addition, the subject device incorporates the latest reconstruction technology, AiCE-i (Advanced intelligent Clear-IQ Engine - integrated), intended to reduce image noise and improve image quality by utilizing Deep Convolutional Neural Network methods. These methods can more fully explore the statistical properties of the signal and noise. By learning to differentiate structure from noise, the algorithm produces fast, high quality CT reconstruction.

**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 Prime 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 Prime SP (TSX-303B/8) V10.2 with AiCE-i** is substantially equivalent to **Aquilion Prime SP, TSX-303B/1, v8.4**, which received premarket clearance under K172188 and is marketed by Canon Medical Systems USA. The changes made to the subject device include the addition of AiCE (Advanced intelligent Clear-IQ Engine), a reconstruction algorithm that utilizes Deep Convolutional

Neural Network methods to reduce image noise and improve image quality. A comparison of the technological characteristics between the subject and the predicate device is included below.

Item	Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i	Aquilion Prime SP (TSX-303B/1) V8.4
510(k) Clearance Number	N/A	K172188
Anatomical Region	AIDR 3D (Whole Body)  AiCE (Abdomen and Pelvis, Chest, Cardiac, Extremities, Brain, Inner ear)	AIDR 3D (Whole Body)
Noise Reduction Processing	AIDR 3D AIDR 3D Enhanced Quantum Denoising Smoothing (QDS) AiCE	AIDR 3D AIDR 3D Enhanced Quantum Denoising Smoothing (QDS)
Processing capability	Console KCCN-020C  Reconstruction processing system (AiCE-i: CSAL-001A)	Console KCCN-017B  Reconstruction processing system (N/A)
Display console kit	CGS-72B (Optional)	CGS-72A: TSX-303B/1 (Optional)
Image Quality Claims	<ul style="list-style-type: none"> <li>- Improved Quantitative high contrast Spatial Resolution over AIDR 3D with reduced noise</li> <li>- Improved Quantitative Dose Reduction over FBP</li> <li>- Better Low-contrast Detectability than AIDR 3D for abdomen at the same dose</li> <li>- Noise appearance/texture more similar to high dose filtered backprojection compared to MBIR</li> </ul>	No change
Operating System	Microsoft Windows 10	Microsoft Windows 7

**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, IEC60601-1-9, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, 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.

### 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 AiCE images are substantially equivalent to the predicate device as demonstrated by the results of the above testing.

A dose reduction study was conducted using AiCE and based on the results, a dose reduction claim of 82%, relative to FBP, is supported as well as 13.8% improved low contrast detectability and noise reduction of 21.4 at the same dose for body compared to AIDR 3D.

### Low Contrast Detectability

A phantom study was conducted in order to support claims of low-contrast detectability of 1.5 mm at 0.3%, 21.8mGy, using AiCE Body

### Noise Texture Reader Study

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:

- "Noise appearance/texture more similar to high dose filtered backprojection compared to MBIR"
- "Noise appearance/texture more similar to filtered backprojection compared to MBIR"
- "Improved noise appearance/texture compared to MBIR"
- "More natural noise texture compared to MBIR"

Representative abdomen/pelvis, lung, cardiac, brain, extremities and inner ear diagnostic images, reviewed by an American Board Certified Radiologist, were obtained using the subject device and it was confirmed that the AiCE reconstructed images were of diagnostic quality.

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 also included as part of this submission.

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.

Additionally, testing of the subject device was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

## **17. CONCLUSION**

The **Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i** 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.