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

December 10, 2020

Re: K203042
Trade/Device Name: Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: October 5, 2020
Received: October 6, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

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

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)*

K203042

Device Name
Aquilion Exceed LB (TSX-202A/3) V10.6 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 Exceed LB 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, 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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K203042

510(k) SUMMARY

1. SUBMITTER'S NAME:
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2. OFFICIAL CORRESPONDENT:
Fumiaki Teshima
Senior Manager, Quality Assurance Department

3. ESTABLISHMENT REGISTRATION:
9614698

4. CONTACT PERSON:
Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

5. DATE PREPARED:
October 5, 2020

6. TRADE NAME(S):
Aquilion Exceed LB (TSX-202A/3) V10.6 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: 21 CFR §892.1750
c) Regulatory Class: Class II

9. PRODUCT CODE / DESCRIPTION:
90JAK / Computed Tomography X-Ray System

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

11. PREDICATE DEVICE:

Product	Marketed by	Regulation Number	Regulation Name	Product Code	510(k) Number	Clearance Date
Primary: 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
Reference Device: Aquilion LB, TSX-201A/3, V6.0	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K150003	03/19/2015

12. REASON FOR SUBMISSION:

New device

13. DEVICE DESCRIPTION:

Aquilion Exceed LB (TSX-202A/3) V10.6 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.

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. The AiCE algorithm has not been modified or retrained since the previous clearance in the predicate, K192832.

14. INDICATIONS FOR USE:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head. The Aquilion Exceed LB 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, extremities, head and inner ear applications.

15. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i** is substantially equivalent to **Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i**, which received premarket clearance under K192832, and is marketed by Canon Medical Systems USA. The intended use of the Aquilion Exceed LB is the same as that of the predicate device. Additionally, **Aquilion LB (TSX-201A/3) V6.0**, is included in this submission as a Reference Device due to its similarity with the subject device with regard to the gantry size opening of 900mm. A comparison of the technological characteristics between the subject and the predicate device is included below.

	Subject Device	Primary Predicate Device
Device Name, Model Number	**Aquilion Exceed LB (TSX-202A/3) V10.6 with AiCE-i**	**Aquilion Prime SP (TSX-303B/8) V10.2 with AiCE-i**
510(k) Number	**This submission**	**K192832**
Scan (Rotation) time	(0.26), 0.4, 0.45, 0.5, 0.6, 0.75, 1, 1.5, 2, 3 s	(0.23), 0.35, 0.375, 0.4, 0.45, 0.5, 0.6, 0.75, 1, 1.5, 2, 3 s
View rate	Max. 2400 views/s (0.5 s)	Max. 2572 views/s (0.35 s)
Scan field diameter (Field of View)	320/550/700 mm	320/500 mm
Extended Field of View	Available	Available
Gantry opening diameter	900 mm	780 mm
Gantry tilt	No tilt	±30° Axial and helical scanning Gantry and remote controlled
Wedge Filter Types	Two types Small: FOV M Large: FOV L and XL	Two types Small: FOV M Large: FOV L
Detector	PURE ViSION detector	PURE ViSION detector
Data acquisition	1136 channels × 80 rows	896 channels × 80 rows
X-ray generation • **Channel-direction (fan) angle** • **Slide-direction (cone) angle** • **Rated output** • **X-ray tube voltage** • **X-ray tube current** • **X-ray tube heat capacity** • **X-ray tube cooling rate**	 52.2° 3.22° Max.72 kW 80/100/120/135 kV 10-500 mA (10-600 mA) 7.5 MHU Max. 1,386 kHU/min (16.5 kW) Actual 1,008 kHU/min (12.0 kW)	 49.2° 3.8° Max.72 kW 80/100/120/135 kV 10-500 mA (10-600 mA) 7.5 MHU Max. 1,386 kHU/min (16.5 kW) Actual 1,008 kHU/min (12.0 kW)
Metal Artifact Reduction	Single Energy Metal Artifact Reduction (SEMAR)	Single Energy Metal Artifact Reduction (SEMAR)
Noise reduction processing	• Quantum Denoising Software (QDS) • Adaptive Integrative Dose Reduction 3D (AIDR 3D) • AIDR 3D Enhanced • AiCE (Body, Lung, Bone, Brain, Inner Ear)	• Quantum Denoising Software (QDS) • Adaptive Integrative Dose Reduction 3D (AIDR 3D) • AIDR 3D Enhanced • AiCE (Body, Lung, Cardiac, Bone, Brain, Inner Ear)
Respiratory-gating system	Available	Available
Couch lateral movement	±85mm	±42mm

16. 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, IEC60601-1-1, 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]

17. TESTING

Risk analysis and verification/validation activities conducted through bench testing demonstrate that the established specifications for the device have been met. These studies compared both FBP and AiCE reconstructions in the predicate and subject devices.

Performance Testing - Bench

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), Standard Deviation of Noise (SD) and Noise Power Spectra (NPS). It was concluded that the Aquilion Exceed LB system demonstrated substantially equivalent or improved performance relative to the predicate device as demonstrated by the results of the above testing.

Dose Reduction with AiCE

A phantom study was conducted using the MITA-FDA LCD Body phantom and the results demonstrated a dose reduction of up 82% for AiCE Abdomen, relative to FBP.

Quantitative Spatial Resolution

A comparison study was conducted, utilizing phantoms, in order to support a quantitative spatial resolution improvement claim of improved high contrast spatial resolution and simultaneous 50% noise reduction with AiCE Body STD.

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 claim, noise appearance/texture is more similar to high dose filtered backprojection, compared to MBIR.

Quantitative Body LCD and Noise Improvement

A phantom study was conducted using the MITA-FDA LCD Body phantom and the results demonstrated 1) 63% improved low contrast detectability and noise reduction of 57.8% with AIDR at the same dose for body compared to FBP and 2) 87% improved low contrast detectability and noise reduction of 67.2% with AiCE at the same dose for body compared to FBP.

PURE ViSION Optics

Phantom studies were conducted using the MITA-FDA LCD Body phantom and the results demonstrated 22% improved in low-contrast detectability and dose reduction of 27.5% at the same dose for Body CT and improved low contrast detectability at the same dose for Brain CT.

Representative clinical images were not necessary to demonstrate substantial equivalence of the subject device.

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.

18. CONCLUSION

The **Aquilion Exceed LB (TSX-202A/3) V10.6 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.