



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

March 24, 2021

Re: K203225

Trade/Device Name: Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: February 18, 2021
Received: February 22, 2021

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

Indications for Use

510(k) Number (if known)
K203225

Device Name

Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System

Indications for Use (Describe)

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head, with the capability to image whole organs in a single rotation. Whole organs include, but are not limited to brain, heart, pancreas, etc.

The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

AiCE 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, brain, inner ear and extremities applications.

The Spectral Imaging System allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid KV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation.

Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies.

When used by a qualified physician, a potential application is to determine the course of treatment.

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

K203225

- 1. SUBMITTER'S NAME:**
Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550
- 2. ESTABLISHMENT REGISTRATION:**
9614698
- 3. OFFICIAL CORRESPONDENT/CONTACT PERSON:**
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Canon Medical Systems Corporation

Orlando Tadeo, Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems USA, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459
- 4. DATE PREPARED:**
October 30, 2020
- 5. TRADE NAME(S):**
Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System
- 6. COMMON NAME:**
System, X-ray, Computed Tomography
- 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 / DESCRIPTION:**
JAK / Computed Tomography X-Ray System
- 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 ONE (TSX-306A/3) V10.0 with Spectral Imaging System	Canon Medical Systems, USA	21 CFR §892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K192828	02/13/2020

11. REASON FOR SUBMISSION:

Modification of existing device to extend the range of the Spectral Imaging System to include cardiac and to improve image quality for existing Spectral scan regions.

12. DEVICE DESCRIPTION:

Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System 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, with the capability to image whole organs in a single rotation. Whole organs include, but are not limited to brain, heart, pancreas, etc.

The Aquilion ONE has the capability to provide volume sets of the entire organ. These volume sets can be used to perform specialized studies, using indicated software/hardware, of the whole organ by a trained and qualified physician.

FIRST is an iterative reconstruction algorithm intended to reduce exposure dose and improve high contrast spatial resolution for abdomen, pelvis, chest, cardiac, extremities and head applications.

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The Spectral Imaging System allows the system to acquire two nearly simultaneous CT images of an anatomical location using distinct tube voltages and/or tube currents by rapid KV switching. The X-ray dose will be the sum of the dose at each respective tube voltage and current in a rotation. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in X-ray attenuation between these distinct energies. When used by a qualified physician, a potential application is to determine the course of treatment.

14. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System** is substantially equivalent to **Aquilion ONE (TSX-306A/3) V10.0 with Spectral Imaging System**, which received premarket clearance under K192828, and is marketed by Canon Medical Systems USA. The intended use of the Aquilion ONE is the same as that of the predicate device. The **Aquilion ONE (TSX-306A/3) V10.4 with Spectral Imaging System** includes changes made to the predicate device including addition of cardiac clinical region for the Spectral Imaging System, addition of marketing claims stating that Spectral offers the ability to optimize iodinated contrast media usage*, and image quality improvements to existing Spectral scan regions.

** Optimization of contrast usage is only recommended within the dosing ranges that appear in approved iodinated contrast drug labeling.*

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 ONE (TSX-306A/3) V10.4 with Spectral Imaging System	Aquilion ONE (TSX-306A/3) V10.0 with Spectral Imaging System	
510(k) Number	This submission	K192828	
Spectral Imaging System (CSDE-004A)	Available	Available	
<ul style="list-style-type: none"> • Scan Type • Scan Regions • Spectral Reconstruction Images • Metal Artifact Reduction (MAR) • ECG-gated scan • Gantry tilt • Rotation time 	<ul style="list-style-type: none"> -Rapid kV Switching -Abdomen and pelvis, Chest, Extremities and Cardiac -Basis material image -Monochromatic image -Iodine Map -VNC (virtual non-contrast) image Available Available Available 0.275, 0.5, 0.75 and 1.0 s 	<ul style="list-style-type: none"> -Rapid kV Switching -Abdomen and pelvis, Chest and Extremities -Basis material image -Monochromatic image -Iodine Map -VNC (virtual non-contrast) image N/A N/A N/A 0.5, 0.75 and 1.0 s 	<ul style="list-style-type: none"> Addition of Cardiac scan region and image quality improvements to existing regions

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.

Spectral Imaging 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)-Wire, Standard Deviation of Noise (SD), Noise Power Spectra (NPS) and Low Contrast Detectability (LCD). It was concluded that the Spectral Images are substantially equivalent to the predicate device as demonstrated by the results of the above testing.

Dose Neutral

A phantom study was conducted using the MITA-FDA LCD Body phantom and the results demonstrated that Spectral 70keV was dose neutral with single energy AIDR 120kVp.

Noise Magnitude Reduction and Texture

A phantom study was conducted using phantoms comparing Spectral 70keV and AIDR 120kVp standard deviation results and it was determined that Spectral 70keV images had 50% noise reduction compared to same dose single energy images.

Contrast to Noise Ratio Improvement

A study using the 33cm Gammex dual energy CT phantom was conducted and it was determined that there was a 150% CNR improvement for iodine with Spectral 70keV relative to single energy AIDR, at the same dose.

Iodine Concentration Reduction

A study using the 33cm Gammex dual energy CT phantom with inserts of varying iodine concentration demonstrated that there was a 60% iodine concentration reduction at 60keV relative to 120kVp single energy AIDR.

Spectral Imaging Performance Testing – Clinical Images

Representative abdomen/pelvis, lung, extremity and cardiac Spectral Images, reviewed by an American Board Certified Radiologist, were obtained using the subject device and it was confirmed that the Spectral Imaging reconstructed images using the subject device 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 ONE (TSX-306A/3) V10.4 with Spectral Imaging System** 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.