Toshiba Medical Systems Corporation
% Orlando Tadeo, Jr.
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc
2441 Michelle Drive
TUSTIN CA 92780

February 23, 2018

Re: K173468
Trade/Device Name: Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: January 10, 2018
Received: January 11, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173468

Device Name

Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0

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 Precision 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.

FIRST 3.0 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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. OFFICIAL CORRESPONDENT:

Naofumi Watanabe
Senior Manager, Regulatory Affairs and Vigilance

3. ESTABLISHMENT REGISTRATION:

9614698

4. CONTACT PERSON:

Orlando Tadeo, Jr.
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Toshiba America Medical Systems, Inc
2441 Michelle Drive
Tustin, CA 92780
(714) 669-7459

5. Date Prepared:

February 20, 2018

6. TRADE NAME(S):

Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0

7. COMMON NAME:

System, X-ray, Computed Tomography

8. DEVICE CLASSIFICATION (Regulatory Class, CFR Reference, Name):

Class II (per 21 CFR 892.1750, Computed Tomography X-ray System)

9. PRODUCT CODE / DESCRIPTION:

JAK / 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
Aquilion PRIME, TSX-303A/A, /B and /F, v6.00 (*Primary Predicate Device*)	Toshiba America Medical Systems	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K141741	11/11/2014
Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1	Toshiba America Medical Systems	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K170177	06/30/2017

12. REASON FOR SUBMISSION:

New medical device

13. DEVICE DESCRIPTION:

Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0 is an ultra-high resolution whole body multi-slice helical CT scanner, consisting of a gantry, couch and a console used for data processing and display. Aquilion Precision incorporates a 160-row, 0.25 mm detector, a 5.7-MHU large-capacity tube, and 0.35 s scanning, enabling wide-range scanning with short scan times to capture cross sectional volume data sets used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician. In addition, the subject device incorporates the latest iterative reconstruction technology, FIRST 3.0, intended to reduce exposure dose while maintaining and/or improving image quality.

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 Precision 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.

FIRST 3.0 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.

15. SUBSTANTIAL EQUIVALENCE:

The **Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0**, is substantially equivalent to the Aquilion PRIME, TSX-303A/A, /B and /F v6.00, which received premarket clearance under K141741 and is marketed by Toshiba America Medical Systems. The intended use of the Aquilion Precision is the same as that of the predicate device. Software applications that have already received 510(k) clearance are being implemented on the subject device. The main difference between the Aquilion Precision and the predicate device is the configuration of the detector as well as the implementation of two new acquisition modes, HR (High Resolution) and

SHR (Super High Resolution), in addition to the conventional, NR (Normal Resolution) mode, which provides the user with image quality improvements. The NR mode is substantially equivalent to the acquisition mode employed by the predicate device. A comparison of the technological characteristics between the subject and the predicate device is included below.

Item	**Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0**	**Aquilion PRIME, TSX-303A/A, /B and /F v6.00**
510(k) Number	This submission	K141741
Configuration of the detector	0.25 mm x 160 rows	0.5 mm x 80 rows
Detector	1792 channels × 160 rows	896 channels × 80 rows
Max. scan length/rotation	40 mm/rotation	40 mm/rotation
Acquisition Modes	NR mode: 0.5mm x 80 rows / 896 channels HR mode: 0.5mm x 80 rows /1792 channels SHR mode: 0.25mm x 160 rows /1792 channels	0.5mm x80 rows /896 channels
Reconstruction Matrix	NR mode: 512×512 HR & SHR mode: 512×512, 1024×1024	512 x 512
FOV (field of view)	320/500mm in diameter	180/240/320/400/500 mm in diameter
Wedge filter Types	Three types Small1:FOV M Large1:FOV L Large2:FOV L	Three types Small :FOV SS, S Medium :FOV M Large :FOV L, LL
X-ray tube capacity Maximum tube cooling rate Continuous tube cooling rate Focal spots size	5.7 MHU 1,026 kHU/min 660 kHU/min Small: Two types Large: Four types	7.5 MHU 1,386 kHU/min 1,008 kHU/min Small: One type Large: One type
CPU memory	256 Gbyte or more	12 Gbyte or more
Image reconstruction time (Max. speed)	Up to 80 images/s (0.0125 s/image)	Up to 30 images/s (0.033 s/image) Option: Up to 60 images/s (0.017 s/image)
Magnetic disk	9.8 TB or more Raw data: 4,000 rotations or more	915 GB or more Raw data: 4000 rotations Image data: 500,000 images

Item	Aquilion Precision (TSX-304A/2) V8.6 with FIRST 3.0	Aquilion PRIME, TSX-303A/A, /B and /F v6.00
510(k) Number	This submission	K141741
	Image data: 2,000,000 images or more (1024 x 1024 pixel images)	
BD-RE(Blu-ray Disc)	25 GB Image data:10,000 images (1024 x 1024 pixel images)	N/A
Noise reduction processing	AIDR 3D AIDR3D Enhanced	QDS AIDR 3D AIDR3D Enhanced
Metal artifact reduction	SEMAR(Volume, Helical) SEMAR (ECG gated)	SEMAR(Volume, Helical) SEMAR (ECG gated)
Gantry opening size Tilt angle	780 mm in diameter ±30°	780 mm in diameter ±30°
Patient Couch Vertical movement: Couch top stroke Frame slide stroke Scan permissible range: Conventional Scan permissible range: Helical Couch-top Speed of movement (fast) Vertical movement stroke Couch-top width Lowest couch height Max. guaranteed weight Footswitch	 2050mm 1750mm 330mm 2000mm 1700mm 1950mm 1650mm 200mm/s 520mm 470mm 420mm 300kg Standard	 2390mm 1890mm N/A 2000mm 1500mm 1950mm 1450mm 200mm/s 568mm 470mm 332mm 300kg Standard
Lateral movement unit Movement speed Lateral Stroke (right and left)	Optional 20mm/s 170mm (85mm in the lateral direction)	Optional 10mm/s 84mm (42mm in the lateral direction)
FIRST 3.0	Optional	N/A

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, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-2-28, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18, 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.

17. TESTING

Risk analysis and verification/validation testing 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 CT number accuracy, contrast-to noise ratio, uniformity, slice sensitivity profile, modulation transfer function, low contrast detectability, standard deviation of noise and noise power spectra. The Aquilion Precision in NR mode is substantially equivalent to the predicate device. The HR and SHR modes yield improved high contrast spatial resolution with some tradeoff in noise and LCD relative to NR mode. The FIRST algorithm demonstrates equivalent or improved image quality relative to FBP for all modes. A high contrast spatial resolution claim of "up to 46.1 lp/cm based upon the 2% of the MTF of images of a wire test object acquired in HR mode, under the axial scan mode and reconstructed with FC90" is supported. As demonstrated by the performance of FIRST at reduced mA values for standard deviation, MTF, and visual LCD as compared to FBP at higher mA values a qualitative claim of Dose Reduction with FIRST is supported.

Confirmation of Spatial Resolution

The spatial resolution claim was confirmed by measuring the MTF results of seven Aquilion Precision systems. It was determined that a high contrast spatial resolution claim of up to 49.5 lp/cm, based upon the 2% of the MTF of images of a wire test object acquired in HR mode and reconstructed with FC90, is supported.

Low Contrast Detectability Equivalence in Normal Resolution vs High Resolution Modes

A study was conducted utilizing the Head and Body MITA-FDA LCD phantoms to establish a baseline LCD value (AUC) in Normal Resolution (NR) mode using a protocol based on Toshiba's standard adult abdomen protocol and standard adult head protocol, with a fixed technique at a clinically realistic CTDI, and reconstructed with Filtered Backprojection (FBP), AIDR STD, AIDR Enhanced, and FIRST. Results of the study demonstrated that scanning in high resolution mode (HR) and in super high resolution mode (SHR) may result in equivalent or a modest increase in X-ray dose as compared to scanning in normal resolution mode (NR).

Size Discrimination Performance

A model observer study was conducted comparing detectability of a 0.5 mm change in object radius in Normal Resolution vs High Resolution mode utilizing the Catphan 10HU contrast rods, 4-9mm in diameter, which demonstrated a 50% improvement in size discrimination with High Resolution mode compared to Normal Resolution mode at the same dose.

Alternatives to clinical images of cardiac and extremities using cardiac stent and cadaver
A study was conducted to provide cadaver and cardiac stent images for certain anatomical regions in lieu of sample clinical images acquired in NR and HR mode since these examples were not available. This study demonstrated that NR mode and predicate device images were substantially equivalent and that the images acquired in HR and SHR modes showed improved spatial resolution as compared to images acquired in NR mode.

Representative diagnostic images, reviewed by an American Board Certified Radiologist, including head, chest, abdomen/pelvis, extremity and cardiac exams were also obtained using the subject device which demonstrates that the device produces images of diagnostic quality and; therefore, performs as intended.

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 Precision (TSX-304A/2) V8.6 with FIRST 3.0** 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.