DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 30, 2017

Re: K170177
Trade/Device Name: Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 26, 2017
Received: May 30, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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)*

K170177

Device Name

Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1

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 2.1 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:

Akinori Hatanaka
Senior Manager, Regulatory Affairs and Vigilance

3. ESTABLISHMENT REGISTRATION:

9614698

4. CONTACT PERSON:

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

5. Date Prepared:

January 17, 2017

6. TRADE NAME(S):

Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1

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 ONE Vision with FIRST 2.0 (CCRS-001B) V7.4	Toshiba America Medical Systems	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K161009	07/22/2016
Aquilion ONE (TSX-305A/3) V7.3	Toshiba America Medical Systems	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K160587	06/09/2016

12. REASON FOR SUBMISSION:

Modification to a previously cleared device

13. DEVICE DESCRIPTION:

Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1 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 Toshiba CT systems. In addition, the subject device incorporates the latest iterative reconstruction technology, FIRST 2.1, 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, 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 2.1 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 ONE (TSX-305A/3) V8.3 with FIRST 2.1**, is substantially equivalent to the Aquilion ONE (TSX-305A/3) V7.3, which received premarket clearance under K160587, marketed by Toshiba America Medical Systems. The changes made to the subject device include the addition

of **FIRST 2.1**, an iterative reconstruction algorithm that allows the exposure dose to be reduced while maintaining and/or improving image quality as seen when using FBP (filtered back projection) and improves spatial resolution over FBP. A comparison of the technological characteristics between the subject and the predicate devices is included below.

Item	**Aquilion ONE (TSX-305A/3) V8.3 with FIRST 2.1**	**Aquilion ONE (TSX-305A/3) V7.3**	**Aquilion ONE Vision with FIRST 2.0 (CCRS-001B) V7.4**
510(k) Number	This submission	K160587	K161009
Exposure Dose Reduction (Anatomical Region)	AIDR 3D (Whole Body) FIRST 2.1 (Abdomen, pelvis, chest, cardiac, extremities and head)	AIDR 3D (Whole Body)	AIDR 3D (Whole Body) FIRST 2.0 (Abdomen, pelvis, chest, cardiac, and extremities)
Quantitative Dose Reduction Claim	Yes	None	Yes
Image Quality Claim	Improved Spatial Resolution over Filtered Back Projection	No Change	Improved Spatial Resolution over Filtered Back Projection
SURE Subtraction Angio	Available	Not Available	New Feature
SURE Subtraction Iodine Mapping	Available	Not Available	New Feature

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, IEC60601-1-4, IEC60601-1-6, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18, NEMA XR-25 and NEMA XR-26. 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. CT image quality metrics were performed, utilizing phantoms, which validated that the subject device is substantially equivalent to the predicate device with regard to spatial resolution, CT number magnitude/uniformity, noise properties and low contrast detectability/CNR performance.

Image Quality Evaluation

CT image quality metrics were performed, utilizing phantoms, which demonstrated that the subject device is substantially equivalent to or demonstrates an improvement to the predicate

device with regard to contrast-to noise ratio, CT number accuracy, uniformity, slice sensitivity profile, modulation transfer function, low contrast detectability, line pair gauge, standard deviation of noise and noise power spectra.

Quantitative Dose Reduction/Spatial Resolution Evaluations

A dose reduction study was conducted and based on the results, a dose reduction claim with the range 59.2 to 82.4% is supported, as well as a claim of dose reduction that demonstrated a 49.2% noise reduction with FIRST on the Aquilion ONE Genesis Edition. In addition, the testing demonstrates superior LCD performance with FIRST.

These claims were evaluated by comparing Toshiba's iterative reconstruction algorithm, FIRST version 2.1, to filtered backprojection on the Aquilion ONE Genesis Edition system. The dose reduction value was established by demonstrating comparability of low contrast detectability at full dose reconstructed with filtered backprojection (FBP), and at reduced dose reconstructed with FIRST 2.1 (IR). A model observer approach which incorporates some aspects of human vision was used for investigation and a non-inferiority analysis conducted. The noise reduction value was established by comparing the standard deviation of noise magnitude at full dose with FBP with the standard deviation of noise magnitude at variety of dose reduction levels using IR. The study was designed to use clinically realistic dose levels (i.e. acquisition techniques).

PUREViSION Optics Quantitative LCD and Noise Improvement

The subject device demonstrated improvements in low contrast detectability and noise reduction at the same dose as evaluated via model observer studies (MITA-FDA LCD Head and MITA-FDA LCD Body phantoms).

SURE Subtraction Angio Evaluation

A clinical evaluation was conducted to assess whether or not the visibility of contrast enhancement was improved using SURE Subtraction Angio over the predicate device. Utilizing a visual assessment scoring method by doctors and clinical case examples it was determined that the visualization of contrast enhancement, especially blood vessels, are improved when compared to the predicate device.

SURE Subtraction Iodine Mapping Evaluation

In order to determine if SURE Subtraction Iodine Mapping functions as intended as an adjunct visualization tool to assess the enhancement of the visibility of contrast agents and the ability to provide additional information of abdominal organs, a clinical evaluation was conducted. Utilizing a visual assessment scoring method of clinical case examples it was determined that SURE Subtraction Iodine Mapping provides additional information for the assessment of abdominal organs, differential enhancement mapping images are useful visualization tools and CE Boost images provide improved CNR.

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.

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 ONE (TSX-305A/3) V8.3 with FIRST 2.1** 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 is substantially equivalent in safety and effectiveness to the predicate device.