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

October 6, 2017

Re: K172188
Trade/Device Name: Aquilion Prime SP, TSX-303B/1, v8.4
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 19, 2017
Received: July 20, 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 (DICE) 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 (DICE) 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,

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)*

K172188

Device Name

Aquilion Prime SP, TSX-303B/1, v8.4

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

5. **Date Prepared:**
   September 27, 2017

6. **TRADE NAME(S):**
   Aquilion Prime SP, TSX-303B/1, v8.4

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   JAK – System, Computed Tomography

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**	**510(k) Number**	**Clearance Date**
Aquilion PRIME, TSX-303A/A, /B and /F, v6.00 (*Primary Predicate Device*)	Toshiba America Medical Systems	K141741	November 11, 2014
Aquilion Lightning SP TSX-036A/1, v8.4	Toshiba America Medical Systems	K170019	February 2, 2017

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

The **Aquilion Prime SP TSX-303B/1** is an 80-row CT System that is intended to acquire and display cross-sectional volumes of the whole body, including the head. This system is based upon the technology and materials of previously marketed Toshiba CT systems.

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 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.

15. SUBSTANTIAL EQUIVALENCE:

The subject device 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 **Aquilion Prime SP TSX-303B/1, v8.4**, incorporates modifications to the cleared device which include changes to the current detector (new wedge filter and new DAS board), modifications to previously cleared optional software applications in order to realize workflow improvements and addition of previously cleared optional software features. These changes do not affect the safety or efficacy of the cleared device, as demonstrated in performance testing. The method of operation and manufacturing process remain unchanged from the cleared device. See below for a brief comparison of the technological characteristics between the subject and the predicate devices:

Item	Aquilion Prime SP TSX-303B/1, v8.4	Aquilion PRIME TSX-303A/A, /B and /F, v6.00
510(k) Number	This submission	K141741
Detector	896 channels × 80 rows PURE Vision	896 channels × 80 rows PURE Vision
Number of detector elements	0.5 mm x 80 rows	0.5 mm x 80 rows
Maximum scan length/rotation	40 mm/rotation	40 mm/rotation
FOV (Field of View)	320/500 mm in diameter	180/240/320/400/500 mm in diameter
Wedge filter types	Two types	Three types
PURE Vision Optics*	Standard	N/A
Processing capability	Hexa-core Xeon 32GB memory or more	Quad-core Xeon 12GB memory or more
Image reconstruction time (Max. speed)	Up to 50 images/s (0.02 s/image) Up to 70 images/s (0.014 s/image) * with optional upgrade	Up to 30 images/s (0.033 s/image) Up to 60 images/s (0.016 s/image) * with optional upgrade
Extended Field of View	Available	Not Available

Modifications to previously cleared software options:

Application	Comment
Variable Helical Pitch (vHP)	Workflow improvements: 3-phase vHP available and for ECG-gated helical scan phase, Modulation can be specified and SUREExposure3D is enabled. Previously cleared under K170019
Dual Energy System Package	Workflow improvement: DE clinical application can be executed during scanning. Previously cleared under K170019
SEMAR (Single Energy Metal Artifact Reduction)	Implementation of Volume ECG-gated scan, previously cleared under K170019

Previously cleared software options being implemented to the modified device:

4D Cerebral Artery Morphological Analysis	Previously cleared under K142465
SURE Subtraction Lung	Previously cleared under K133324
Scan Protocol Management	Previously cleared under K142465

*PUREVision Optics, based upon the new wedge filters in combination with the PUREVision detector, afford the system with an optimized beam spectrum and the filtration of low energy photons for a more homogeneous x-ray spectrum. Previously cleared under K170177

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 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 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 are included in this submission which demonstrates that the requirements for the modifications made to the system have been met. The modified system was evaluated to assess spatial resolution, axial slice thickness/slice sensitivity profile, CT number magnitude/uniformity, noise properties, low contrast detectability and contrast-to-noise ratio performance and it was determined that the subject device demonstrates equivalent or slightly improved image quality characteristics.

Quantitative Dose Reduction and Spatial Resolution Evaluation

A dose reduction study was conducted using AIDR 3D Enhanced and based on the results, a dose reduction claim with the range 51% to 75% is supported while simultaneously preserving low contrast detectability and high contrast spatial resolution

PURE ViSION Optics Quantitative LCD and Noise Improvement

Studies were conducted comparing the subject device with PURE Vision Optics versus the predicate device to assess dose reduction and LCD/Noise improvements using filtered backprojection (FBP) on both systems. The results of the studies demonstrated a quantitative dose reduction of 20%-31%, improvements in low contrast detectability for head (range 13%-19%), improvements in low contrast detectability for body (range 15%-22%) and noise reduction of 13% at the same dose as evaluated via model observer studies (MITA-FDA LCD Head and MITA-FDA LCD Body phantoms).

Representative diagnostic images, reviewed by an American Board Certified Radiologist, including head, chest, abdomen and peripheral 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 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 modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

18. CONCLUSION

The modifications incorporated into the **Aquilion Prime SP TSX-303B/1, v8.4** do not change the indications for use or the intended use of the device. Based upon bench testing, representative clinical images, successful completion of software validation and application of risk management and design controls, it is concluded that the subject device has demonstrated substantial equivalence to the predicates and is safe and effective for its intended use.