DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 2, 2017

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

Re: K170019
Trade/Device Name: Aquilion Lightning, TSX-036A/1, V8.4
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 30, 2016
Received: January 3, 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 yours,

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)*

K170019

Device Name

Aquilion Lightning, TSX-036A/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 Lightning 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.

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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:**
   Toshiba Medical Systems Corporation
   1385 Shimoishigami
   Otawara-Shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT:**
   Akinori Hatanaka
   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:**
   January 31, 2017

6. **TRADE NAME(S):**
   Aquilion Lightning, TSX-036A/1, V8.4

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

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750, Computed Tomography X-ray System)

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
Aquilion Lightning, TSX-035A/4 and /5, V7.0	Toshiba America Medical Systems	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K151263	April 1, 2016
Aquilion PRIME TSX-303A/F, V6.0	Toshiba America Medical Systems	21 CFR 892.1750	Computed Tomography X-ray System	JAK: System, X-ray, Tomography, Computed	K141741	November 26, 2014

12. REASON FOR SUBMISSION:

New device

13. DEVICE DESCRIPTION:

The **Aquilion Lightning, TSX-036A/1, v8.4** 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 Lightning 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 **Aquilion Lightning, TSX-036A/1, v8.4**, is substantially equivalent to the Aquilion Lightning, TSX-035A/4 and /5, v7.0, which received premarket clearance under K153263 and the Aquilion PRIME, TSX-303A, V6.0, which received premarket clearance under K141741, both of which are marketed by Toshiba America Medical Systems. The **Aquilion Lightning, TSX-036A/1, v8.4**, incorporates modifications to the cleared device including implementation of the CT detector previously cleared under K141741 (increases the available detector rows from 16 to 80), a change to the wedge filter and modifications to previously cleared optional software applications in order to realize workflow improvements. 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 for the Aquilion Lightning 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 Lightning, TSX-036A/1, V8.4	Aquilion PRIME TSX-303A/F, V6.0	Aquilion Lightning, TSX-035A/4 and /5, V7.0
510(k) Number	This submission	K141741	K153263
Gantry Rotation Speed (max)	0.75 sec/rotation (Option: 0.5 sec/0.6 sec)	0.35 sec/rotation	0.75 sec/rotation (Option: 0.5 sec/0.6 sec)
Detector	896 channels x 80 rows PUREVision	896 channels x 80 rows PUREVision	800 channels × 16 rows PUREVision
Slices/rotation	40 [(*Software limits acquisition to 40 slices*) 80 w/ double slice upgrade] 80 (160 w/ double slice and dynamic volume upgrade)	40 [(*Software limits acquisition to 40 slices*) 80 w/ double slice upgrade] 80 (160 w/ double slice and dynamic volume upgrade)	16 (32 w/ double slice upgrade)
Scan length/rotation	40 mm	40 mm	20 mm
FOV (field of view) diameter	320/500mm	180/240/320/400/500mm	180/240/320/390/500mm
Wedge filter types	Two types	Three types	Three types
X-ray rated output **X-ray tube voltage** **X-ray tube current** **X-ray fan angle** **X-ray cone angle**	Max. 36 kW (Option: Max. 50.4kW) 80/100/120/135 kV 10-300 mA (Option: 10-420 mA) 49.2° 3.8°	60 kW (Option: Max 72 kW) 80/100/120/135 kV 10-300 mA (Option: 10-420 mA) 49.2° 3.8°	Max. 36 kW (Option: Max. 50.4kW) 80/100/120/135 kV 10-300 mA (Option: 10-420 mA) 43.9° 1.9°
Noise reduction processing	QDS, AIDR 3D , AIDR3D Enhanced	QDS, AIDR 3D , AIDR3D Enhanced	QDS, AIDR 3D , AIDR3D Enhanced
Metal Artifact Reduction	SEMAR (Helical and Volume Scan)	SEMAR (Helical and Volume Scan)	SEMAR (Helical Scan)
Gantry opening size (diameter)	780 mm	780 mm	780 mm
Tilt angle	±30°	±30°	±30°
Variable helical pitch	Optional (2 or multi-phase)	Optional (2-phase)	Optional (2-phase)
Patient couch	205kg/300kg	205kg/300kg	205kg/300kg
Lateral movement kit	Available	Available	Not Available
Installation area (Short patient couch)	Minimum 18.3 m² (15.5 m²)	Minimum 20 m² (19.5 m²)	Minimum 17.2m² (14.4 m²)

Modifications to previously cleared software options:

Application	**Comment**
CT Fluoroscopy	Workflow improvement: Max speed limit on couch-top movement increased and time from scan completion to start button illumination has been reduced
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
SURESubtraction Ortho	Workflow improvement: positioned matched images can be subtracted
Dual Energy System Package	Workflow improvement: DE clinical application can be executed during scanning

Previously cleared software options being implemented to the modified device:

CT Cardiac Function Analysis Software	Previously cleared under K023760
SUREPlaque	Previously cleared under K043111
ECG-Gating Reconstruction System	Previously cleared under K991766
Scan Protocol Management	Previously cleared under K142465
4D Airways Analysis	Previously cleared under K143294
Body Perfusion	Previously cleared under K090504

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 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 are included in this submission which demonstrates that the established specifications for the device have been met. CT image quality metrics were performed, utilizing phantoms, which demonstrated that the subject device is substantially equivalent to the predicate device with regard to spatial resolution, CT number magnitude and uniformity, noise properties, low contrast detectability and CNR performance.

Representative diagnostic images, reviewed by an American Board Certified Radiologist, including head, chest, abdomen, pelvis 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 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 Lightning, TSX-036A/1, v8.4**, performs in a manner similar to and is intended for the same use as the predicate devices, as indicated in product labeling. Based upon bench testing, successful completion of software validation and application of risk management and design controls, it is concluded that the subject device is substantially equivalent in safety and effectiveness to the predicate devices.