DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

March 10, 2015

Re: K142465
Trade/Device Name: Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: February 9, 2015
Received: February 11, 2015

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K142465

Device Name
Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0

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.

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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TOSHIBA
Leading Innovation

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

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:**
   February 9, 2015

6. **TRADE NAME(S):**
   Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0

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 DEVICES:

Product	Marketed by	510(k) Number	Clearance Date
Aquilion ONE Vision, TSX-301C/1 and 301C/2, v6.00	Toshiba America Medical Systems	K132222	November 7, 2013
Aquilion ONE Vision, TSX-301C/3, 301C/4 and 301C/5, v6.00	Toshiba America Medical Systems	K133497	February 10, 2014

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

The **Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0** are whole body CT scanners that capture cross sectional volume data sets used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician. These systems are 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, 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.

15. SUBSTANTIAL EQUIVALENCE:

The **Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0** is substantially equivalent to Aquilion ONE Vision, TSX-301C/1 and 301C/2, v6.00 and Aquilion ONE Vision, TSX-301C/3, 301C/4 and 301C/5, v6.00**,** which were cleared via Pre-Market Notification 510(k), K132222 and K133497, respectively. The **Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0**, incorporates modifications to the cleared device which include a new AIDR 3D selection (AIDR 3D Enhanced), the introduction of two new clinical applications, the availability of Single Energy Metal Artifact Reduction in Helical scan mode, the addition of SurekV with SURE Exposure 3D and scan protocol management. The method of operation and manufacturing process of the CT system remain unchanged from the cleared device.

A complete comparison table is included in this submission. See below for a brief summary of changes:

Item	**Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0**	**Aquilion ONE Vision** TSX-301C/1, /2 v6.00	**Aquilion ONE Vision** TSX-301C/3, /4, /5, v6.00	**Comments**
510(k) Number	This submission	K132222	K133497	
Noise reduction processing	AIDR 3D AIDR 3D Enhanced	AIDR 3D	AIDR 3D	New selection added (Enhanced)
Metal artifact reduction	Volume Scan Helical Scan	Volume Scan	Volume Scan	Helical scan added

Item	**Aquilion ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0**	**Aquilion ONE Vision** TSX-301C/1, /2 v6.00	**Aquilion ONE Vision** TSX-301C/3, /4, /5, v6.00	**Comments**
Dose modulation	SURE Exposure 3D Sure kV	SURE Exposure 3D	SURE Exposure 3D	Feature enhancement
4D Orthopedic Analysis	Optional	N/A	N/A	New application
4D Cerebral Artery Morphological Analysis	Optional	N/A	N/A	New application
Detector	Up to 10% noise reduction *	N/A	Up to 10% noise reduction *	* Applicable configurations

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, IEC60601-1-9, 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 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, utilizing phantoms, to demonstrate that the image quality metric of AIDR 3D Enhanced versus current AIDR 3D is substantially equivalent to or better than the predicate device with regard to spatial resolution, CT number and contrast-to-noise ratio, noise properties and standard deviation of noise. Bench studies were also conducted to confirm that the SurekV feature selects the appropriate kV, to confirm that SEMAR functions similarly, with regard to image quality, when used in Volume and in Helical scan modes and that applicable configurations utilizing the ^{PURE}Vision detector demonstrate improved noise reduction.

Additionally, clinical evaluations were conducted to demonstrate that the new applications 4D Orthopedic Analysis and 4D Cerebral Artery Morphological Analysis, perform as intended. The results confirmed that the applications were comparable to manual measurements and/or segmentations.

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 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 ONE Vision, TSX-301C/1, /2, /3, /4, /5, /6, /7, /8, v7.0** do not change the indications for use or the intended use of the device. 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 devices.