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

510(k) SUMMARY

FEB 10 2014

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   January 21, 2014

6. **TRADE NAME(S):**
   Aquilion ONE Vision, TSX-301C/3, 301C/4 and 301C/5, v6.00

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 ONE Vision, TSX-301C/1 and 301C/2, v6.00	Toshiba America Medical Systems	K132222	November 7, 2013

12. **REASON FOR SUBMISSION:**
    Modification of a cleared device

13. DEVICE DESCRIPTION:

The **Aquilion ONE Vision, TSX-301C/3** and **301C/4, v6.00** are 320-row CT Systems and the **TSX-301C/5, v6.00** is a 160-row CT system consisting of the same gantry, couch and console used for data processing and display. These devices 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:

This device is substantially equivalent to the Aquilion ONE Vision, TSX-301C/1 and 301C/2, v6.00 which was cleared via Pre-Market Notification 510(k), K132222, marketed by Toshiba America Medical Systems. The **Aquilion ONE Vision, TSX-301C/3, 301C/4 and 301C/5, v6.00**, incorporates modifications to the cleared device which include implementation of a new detector that meets the specifications of the current detector and software controls that limit the data acquisition in the TSX-301C/5 configuration. 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 from Aquilion ONE Vision, TSX-301C/1 and 301C/2, v6.00:

Item	**Aquilion ONE Vision TSX-301C/3, 301C/4 and 301C/5 v6.00**	**Aquilion ONE Vision** TSX-301C/1 and 301C/2 v6.00	**Comments**
510(k) Number	This submission	K132222	
Number of detector elements	320 x 0.5 mm rows	320 x 0.5 mm rows	No Change
Maximum scan slice thickness	0.5mm x 320 slices (TSX-301C/3 and TSX-301C/4) 0.5mm x 160 slices (TSX- 301C/5)	0.5mm x 320 slices	Software controls limit data acquisition

The following applications have been implemented with the subject device:
Neuro Package (K072693), Vessel View (K063184), Body Perfusion (K090504), Colon View (K090220), Lung Volume Analysis (K113715), Sure Cardio Scoring (K072737), CT Cardiac Function Analysis Software (K023760), Sure Plaque (K043111)

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 to assess detector sensitivity, which demonstrated an improvement and image quality metrics, utilizing phantoms, which validated that the subject device is substantially equivalent to the predicate device with regard to spatial resolution, CT number and contrast-to-noise ratio, noise properties and uniformity performance. Additionally, representative diagnostic images, reviewed by an American Board Certified Radiologist, including brain, chest, abdomen and peripheral exams were 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 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/3, 301C/4 and 301C/5, v6.00** 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.

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 10, 2014

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780 US

Re: K133497
Trade/Device Name: Aquilion ONE Vision, TSX-301C/3, 301C/4 and 301C/5, v6.00
Regulation Number: 21 CFR 892.1750
Regulation Name: System, Computed Tomography, X-Ray
Regulatory Class: II
Product Code: JAK
Dated: November 12, 2013
Received: November 14, 2013

Dear Mr. Biggins:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133497

Device Name: **Aquilion ONE Vision, TSX-301C/3, 301C/4 and 301C/5, v6.00**

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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K133497_____