



September 5, 2014

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

Re: K134025

Trade/Device Name: Aquilion ONE Vision Self-Propelled Scan Base Kit for IVR-CT,
CGBA-033A

Regulation Number: 21 CFR 892.1750

Regulation Name: Computed tomography x-ray system

Regulatory Class: II

Product Code: JAK

Dated: July 29, 2014

Received: July 30, 2014

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 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

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)

K134025

Device Name

Aquilion ONE Vision Self-Propelled Scan Base Kit for IVR-CT, CGBA-033A

Indications for Use (Describe)

Optional movable gantry base unit for use with an Aquilion ONE (TSX-301C) system to support longitudinal movement and allow acquisition of images in the z-direction (Z-axis).

Note: When installed with the movable gantry base unit, Aquilion ONE can be used with the INFX-8000C system in the same room.

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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510(k) SUMMARY

- 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 Self-Propelled Scan Base Kit for IVR-CT, CGBA-033A
- 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 DEVICES:**

Product	Marketed by	510(k) Number	Clearance Date
Aquilion LB Movement Base Kit	Toshiba America Medical Systems	K111633	August 25, 2011
Aquilion ONE Vision, TSX-301C/1, v4.90	Toshiba America Medical Systems	K122109	September 21, 2012
INFX-8000C	Toshiba America Medical Systems	K113052	November 22, 2011

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

The **Aquilion ONE Vision Self-Propelled Scan Base Kit for IVR-CT, CGBA-033A** is an optional kit intended to be used in conjunction with an Aquilion ONE Vision / INFX-8000C based IVR-CT system. The subject device is attached to the CT gantry to support longitudinal movement and allow image acquisition in the z-direction (Z-axis), both axial and helical. When this option is selected, the standard CT patient couch is replaced with the patient handling system utilized by the interventional x-ray system, Toshiba INFX-8000C. The intended uses and technological characteristics of the Aquilion ONE Vision CT System and INFX-8000C Interventional X-Ray System with which this device is used, remain the same.

14. INDICATIONS FOR USE:

Optional movable gantry base unit for use with an Aquilion ONE (TSX-301C) system to support longitudinal movement and allow acquisition of images in the z-direction (Z-axis).

Note: When installed with the movable gantry base unit, Aquilion ONE can be used with the INFX-8000C system in the same room.

15. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aquilion LB Movement Base Kit, CGBA-014A, which received premarket clearance under K111633, marketed by Toshiba America Medical Systems.

The **Aquilion ONE Vision Self-Propelled Scan Base Kit for IVR-CT, CGBA-033A**, incorporates modifications to the cleared device in order for the self-propelled scan base unit to be connected to an Aquilion ONE Vision gantry. This allows the CT system to acquire images in the z-direction (Z-axis) when a fixed catheterization table is used for patient support instead of a dedicated CT patient couch. Additional modifications allow scanning in the IN and OUT directions rather than just in the OUT direction. The indications for use, method of operation including the imaging chain, base software and manufacturing process of the CT and Interventional XR systems remain unchanged from the cleared devices.

A complete comparison table is included in this submission. See below for a brief summary of changes from Aquilion LB Movement Base Kit, CGBA-014A:

Item	Aquilion ONE Vision Self-Propelled Scan Base Kit for IVR-CT, CGBA-033A	Aquilion LB Movement Base Kit, CGBA-014A	Comments
CT System	Aquilion ONE Vision	Aquilion LB	Changed
Gantry drive	Movement along rails laid on the floor	Movement along rails laid on the floor	Same
Cabling	Floor cabling	Roof cabling	Changed
Couch	Fixed catheterization table (INFX-8000C System)	Dedicated couches	Changed
Scan direction	IN/OUT directions	OUT direction only	Changed
Direction of Scanogram acquisition	IN/OUT directions	OUT direction only	Changed

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, IEC60601-1-8, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18 and NEMA XR-25. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

17. NON-CLINICAL TESTS

This submission includes summary tables detailing the risk analysis and verification/validation testing conducted through bench testing which demonstrates that the requirements for the modifications made to the system have been met. Evaluation of the modified device included, but was not limited to, confirmation that base movement speed, scanogram and axial/helical scan functions, and interlocks including contact detection, performed according to specifications.

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 Self-Propelled Scan Base Kit for IVR-CT, CGBA-033A**, do not change the indications for use or the intended use of the previously cleared devices. 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 safe and effective for its intended use and is substantially equivalent to the predicate device.