K121553

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 26 2012

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. **TRADE NAME(S):**
   TSX-101A/R; Aquilion RXL

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

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

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

9. **PERFORMANCE STANDARD:**
   21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

10. **PREDICATE DEVICE:**
    TSX-301A/2 – K093891

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

12. **DEVICE DESCRIPTION:**
    The TSX-101A/R is a whole body CT scanner. This device captures helical volumetric data sets. The device consists of a gantry, patient couch (table) and peripheral cabinets used for data processing and display.

13. SUMMARY OF INTENDED USES:

This device is indicated to acquire and display cross sectional volumes of the whole body, to include the head.

The Aquilion RXL 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.

14. SUBSTANTIAL EQUIVALENCE:

The modification to this device is to reduce radiation exposure to the patient. The modification allows for the use of an iterative reconstruction algorithm that provides the user the ability to perform scans at lower doses. The materials, hardware, method of operation, base software and manufacturing processes remain unchanged from the cleared device; TSX301A/2 (k093891).

New feature	
Maximum number of slices	Changed from 16 to 32
Application of AIDR algorithm	Not available on previous version
Active Collimation	Not available on previous version.
Improved Computational Hardware	Updated computer and associated hardware from previous version.

15. 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 standards and its collateral standards. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

16. SUMMARY OF TESTING:

Testing was conducted utilizing phantoms and accepted image quality metrics. The results of this testing is contained in the user information for the device. Additional testing was conducted at numerous beta sites to provide clinical data for the validation of the software change.

17. CONCLUSION

The additional features that are being added to the Aquilion RXL at this time do not change the indication for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to this modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 26 2012

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

Re: K121553
Trade/Device Name: Aquillion RXL; TSX-101A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 24, 2012
Received: May 25, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: Aquilion RXL; TSX-101A

Indications for Use:

This device is indicated to a acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion RXL 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.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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