510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

AUG 25 2011

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):**
   Aquilion LB Movement Base Kit, CGBA-014B

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

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

8. **PRODUCT CODE / DESCRIPTION:**
   JAK – Computed tomography X-ray system

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

10. **PREDICATE DEVICE:**
    TSX-201A, Aquilion LB CT Scanner (K050458)

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

12. **DEVICE DESCRIPTION:**
    This device is an optional kit that is attached to the gantry to provide z-axis image acquisitions, both axial and helical. When this option is selected the standard CT patient couch is replaced with a multipurpose patient handling system.

13. SUMMARY OF INTENDED USES:

When this device is installed, scanning (including helical scanning) and scanoscopy can be performed without patient couch movement.

14. SUBSTANTIAL EQUIVALENCE:

The Aquilion LB Movement Base Kit is an option that will be offered to customers that require this type of device. The change adds an optional gantry moving base and allows the removal of a dedicated CT Patient Couch. These changes do not affect the previously cleared indication for use for the Toshiba Aquilion LB CT Scanner (TSX-201A). Both devices are considered substantially equivalent.

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 an initial report.

16. CONCLUSION

The Aquilion LB Movement Base Kit (CGBA-014B) complies with the same or equivalent standards and has the same intended use as the predicate device.

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

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

AUG 25 2011

Re: K111633
Trade/Device Name: Aquilion LB Movement Base Kit, CGBA-014B
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 10, 2011
Received: June 13, 2011

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,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111633

Device Name: Aquilion LB Movement Base Kit, CGBA-014B

Indications for Use:

Optional movable gantry base unit for use with the Aquilion LB CT Scanner to support the longitudinal movement and allow the acquisition of images in the z-direction (Z-axis).

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 CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K111633

Page 1 of _____