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

May 15, 2015

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

Re: K143294
Trade/Device Name: Adaptive Motion Correction, CSMC-001A and 4D Airways Analysis, CSAA-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 23, 2015
Received: April 24, 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 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)*

K143294

Device Name

Adaptive Motion Correction (AMC), CSMC-001A, and 4D Airways Analysis, CSAA-001A

Indications for Use *(Describe)*

Adaptive Motion Correction (AMC) software is intended to be used as an adjunct to the current cardiac reconstruction methods in cases where motion of the coronary arteries creates artifacts. This software can be applied to these images, without additional dose to the patient, to enhance the visibility of the coronary arteries.

4D Airways Analysis is a post processing software that may be used in conjunction with chest CT images to provide automatic (semi-automatic) segmentation of the bronchial tree. This software may aid in the diagnosis and follow-up treatment of bronchial diseases.

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.

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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:**
   January 9, 2015 (Updated May 12, 2015)

6. **TRADE NAME(S):**
   Adaptive Motion Correction (AMC) and 4D Airways Analysis

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:**
    None

11. **PREDICATE DEVICES:**

Product	Marketed by	510(k) Number	Regulation Reference	Product Code	Clearance Date
THORACIC VCAR	GE Healthcare	K103480	21 CFR 892.2050	90LLZ	March 7, 2011
CardIQ Xpress 2.0 with SnapShot Freeze Option	GE Healthcare	K120910	21 CFR 892.1750	90JAK	June 18, 2012

12. REASON FOR SUBMISSION:

New software applications intended to be used with 510(k) cleared Aquilion ONE CT systems which have system software V7.0 or later installed.

13. DEVICE DESCRIPTION:

Adaptive Motion Correction (AMC), CSMC-001A, is a reconstruction method available on 320 row Aquilion ONE CT systems, which have system software V7.0 or later installed, to aid physicians in analysis of CT coronary angiography images for diagnosis and treatment planning.

4D Airways Analysis, CSAA-001A, is a post-processing software used on 320 row Aquilion ONE CT systems, which have system software V7.0 or later installed, to aid physicians in analysis of chest CT images for diagnosis and treatment planning.

14. INDICATIONS FOR USE:

Adaptive Motion Correction (AMC) software is intended to be used as an adjunct to the current cardiac reconstruction methods in cases where motion of the coronary arteries creates artifacts. This software can be applied to these images, without additional dose to the patient, to enhance the visibility of the coronary arteries.

4D Airways Analysis is a post processing software that may be used in conjunction with chest CT images to provide automatic (semi-automatic) segmentation of the bronchial tree. This software may aid in the diagnosis and follow-up treatment of bronchial diseases.

15. SUBSTANTIAL EQUIVALENCE:

Adaptive Motion Correction (AMC) is substantially equivalent to and performs in a manner similar to CardIQ Xpress 2.0 with SnapShot Freeze Option, with regard to motion correction (both devices are intended to reduce coronary artery motion blurring) and anatomical region of use. 4D Airways Analysis is substantially equivalent to and performs in a manner similar to the predicate device, Thoracic VCAR**,** in that both devices may be used to provide segmentations of the airways and to display various measurements including luminal area/diameter, bronchial area and wall area.

Item	**Adaptive Motion Correction (AMC)**	**CardIQ Xpress 2.0 with SnapShot Freeze Option**
510(k) Number	This submission	K103480
Anatomical region (CT field of view)	Cardiac	Cardiac
Segmentation area	Coronary arteries	Coronary arteries
Motion estimation parameter	Motion path	Motion path and velocity of the coronary arteries
Registration for motion estimation	Non-rigid registration	Non-rigid registration

Item	4D Airways Analysis	Thoracic VCAR
510(k) Number	This submission	K120910
Anatomical region (CT field of view)	Chest	Chest
Target for measurement	Airways	Airways and lungs
Target for Input data	Multiple volumes	Single volume
Measurement	Lumen diameter and wall area	Lumen diameter and wall area

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 IEC62304 and IEC62366.

17. TESTING

Hazard analysis, verification/validation and performance testing conducted through bench testing are included in this submission which demonstrates that the design specifications established for the device have been met.

For both software features clinical evaluations were performed by qualified users to ensure that the final images presented met user needs. The clinical evaluation of the Adaptive Motion Correction software demonstrated improved visualization of the coronary arteries with the exception of RCA. The clinical evaluation of the 4D Airways Analysis software demonstrated that the user variability associated with this type of measurement was reduced.

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.

18. CONCLUSION

Adaptive Motion Correction (AMC) and 4D Airways Analysis, perform in a manner similar to and are intended for similar use as the predicate devices. 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.