



Food and Drug Administration
10903 New Hampshire Avenue
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July 13, 2015

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

Re: K151091

Trade/Device Name: Vitrea Software Toshiba Package, VSTP-001A
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 22, 2015
Received: April 23, 2015

Dear Mr. Tadeo:

This letter corrects our substantially equivalent letter of July 13, 2015.

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned to the left of the typed name.

For

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

Indications for Use

510(k) Number (if known)

k151091

Device Name

Vitreia Software Toshiba Package, VSTP-001A

Indications for Use (Describe)

Vitreia Software Toshiba Package is an application package developed for use on Vitrea, a medical image processing software, which includes the following post-processing software applications.

CT/XA Cerebral Artery Morphological Analysis

This software is intended to facilitate the extraction and segmentation of user identified aneurysms on the cerebral arteries. The software can be used as an adjunct to diagnosis for the purposes of measurement of size and aspect ratio.

MR Wall Motion Tracking

This application is intended to assist physicians with performing cardiac functional analysis based upon magnetic resonance images. It provides measurements of global and regional myocardial function that is used for patients with suspected heart disease.

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:

April 30, 2015 (Updated 07/07/2015)

6. TRADE NAME(S):

Vitrea Software Toshiba Package, VSTP-001A

7. COMMON NAME:

Radiological Image Processing Software

8. DEVICE CLASSIFICATION:

Class II (per 21 CFR 892.2050, Picture Archiving and Communications System)

9. PRODUCT CODE / DESCRIPTION:

90LLZ / Picture Archiving and Communications System

10. PERFORMANCE STANDARD:

None

11. PREDICATE DEVICES:

Device Name	Vitrea, Version 7.0 Medical Image Processing Software	MRT-301/A5, Vantage Titan 3T, v2.0 (<i>Reference Device</i>)	Aquilion ONE Vision, V7.0 (<i>Reference Device</i>)
Application Name		Cardiac Analysis Application For Superconducting MRI System	4D Cerebral Artery Morphological Analysis
Marketed By	Vital Images, Inc.	Toshiba America Medical Systems	Toshiba America Medical Systems
510(k) Clearance Number	K150258	K120487	K142465
Clearance Date	March 5, 2015	May 23, 2012	March 10, 2015
Product Code	LLZ, Picture Archiving and Communications System	LNH, Magnetic Resonance Diagnostic Device	JAK, Computed Tomography X-Ray System

12. REASON FOR SUBMISSION:

Adding existing software applications to an imaging workstation (Vitrea; Product Code LLZ). MR Wall Motion Tracking includes an improved Contour Tracking function which allows for heart wall strain analysis. CT/XA Cerebral Artery Morphological Analysis allows for the import of volume data from an interventional system in addition to the cleared CT volume analysis.

13. DEVICE DESCRIPTION:

Vitrea Software Toshiba Package, VSTP-001A, an application package developed for use on Vitrea, a medical image processing software, marketed by Vital Images, Inc. Vitrea Software Toshiba Package, VSTP-001A, includes two post processing applications, CT/XA Cerebral Artery Morphological Analysis and MR Wall Motion Tracking, which use brain and cardiac image data, obtained from CT/XA/MR systems, to assist physicians in performing specialized measurements and analysis.

14. INDICATIONS FOR USE:

Vitrea Software Toshiba Package is an application package developed for use on Vitrea®, a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea has the following additional indications:

The CT/XA Cerebral Artery Morphological Analysis application is intended to facilitate the extraction and segmentation of user identified aneurysms on the cerebral arteries. The software can be used as an adjunct to diagnosis for the purposes of measurement of size and aspect ratio.

The MR Wall Motion Tracking application is intended to assist physicians with performing cardiac functional analysis based upon magnetic resonance images. It provides measurements of global and regional myocardial function that is used for patients with suspected heart disease.

15. SUBSTANTIAL EQUIVALENCE:

The software applications included in the Vitrea Software Toshiba Package, VSTP-001A, perform in a manner similar to and are intended for the same use as the predicate devices. These applications include modifications to the originally cleared devices, 4D Cerebral Artery Morphological Analysis (K142465) and Cardiac Analysis Application For Superconducting MRI System (K120487), in order to be available on the Vitrea, Medical Image Processing Software (K150258). The subject and predicate device applications are all post processing applications used to aid physicians with performing specialized measurement and analysis of CT, XA and MR image data.

Complete comparison tables are included in this submission. See below for a brief summary of technological characteristics of the software applications:

Item	CT/XA Cerebral Artery Morphological Analysis	4D Cerebral Artery Morphological Analysis for Aquilion ONE
510(k) Clearance	Subject Device	K142465
Type of Input Data	One volume acquired by X-ray CT system or interventional angiography system	Multiple volumes acquired by X-ray CT system
Anatomical Region	Cerebral Artery	Cerebral Artery
Segmentation (Extraction Of Aneurysm-Shaped Region)	Semi-Automatic Segmentation With One-Clicked Seed Point	Semi-Automatic Segmentation with One-Clicked Seed Point
Measurement (Distance, Angle, Length)	Automatic	Automatic

Item	MR Wall Motion Tracking	Cardiac Analysis Application For Superconducting MRI System
510(k) Clearance	Subject Device	K120487
Anatomical Region	Cardiac	Cardiac
Myocardium Contour Detection	Contour tracking	Contour detection applied to all phases individually
Global Cardiac Function Analysis	Ejection Fraction, Cardiac Output, Volume Curves are calculated from shapes of myocardial contours.	Ejection Fraction, Cardiac Output, Volume Curves are calculated from shapes of myocardial contours.
Regional Wall Motion Analysis	Wall motion, Wall thickness, Wall thickening are calculated	Wall motion, Wall thickness, Wall thickening are calculated
Strain Analysis	Strain is calculated	None

Result Display	Cine View, Polar Map Of Measurement Results Time-Curve Of Regional Measurement	Cine View, Polar Map Of Measurement Results Time-Curve Of Regional Measurement
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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

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrates that the requirements for the applications have been met. Bench studies were conducted using numerical phantoms to analyze the accuracy of extraction/display of aneurysm shaped regions as well as measurement calculations and to analyze cardiac function and strain. Additionally, clinical evaluations were conducted to demonstrate that the CT/XA Cerebral Artery Morphological Analysis and MR Wall Motion Tracking applications performed as intended. The results confirmed that CT/XA Cerebral Artery Morphological Analysis was comparable to manual measurements and/or segmentations and that the contour tracking process of the MR Wall Motion Tracking application met the required success ratio.

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

The software applications included in the Vitrea Software Toshiba Package, VSTP-001A, perform in a manner similar to and are intended for the same 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.