510(k) Summary

1. **SUBMITTER'S NAME**
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3. **ESTABLISHMENT REGISTRATION**
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5. **DATE PREPARED**
   March 19, 2018

6. **TRADE NAME(S)**
   Vitrea Software 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**

Application	Predicate	510(k) Control#	Status
MR Wall Motion Tracking	VSTP-001A	K151093	Cleared
Cerebral Aneurysm Analysis (CT/XA Cerebral Artery Morphological Analysis)	VSTP-001A	K151093	Cleared
MR Coronary Tracking	VSTP-001A	K171222	Cleared
SUREVolume Synthesis	VSTP-001A[1]	K173088	Cleared
Angio Viewer	VSTP-001A	K173088	Cleared
US Cardiac Fusion	VSTP-001A	K173088	Cleared
Ultrasound Application Package	Aplio-i, TUS-i900[2]	K173090	Cleared

[1]Primary Predicate Device VSTP-001A - K173088

[2]Secondary Predicate Device Aplio-i; TUS-i900 –K173090

12. REASON FOR SUBMISSION

Modification - Porting of application software from a different class device.

13. DEVICE DESCRIPTION

Vitrea Software 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, currently includes seven post processing applications, CT/XA Cerebral Artery Morphological Analysis, MR Wall Motion Tracking, MR Coronary Tracking and Ultrasound Applications Package, which use brain, body or cardiac image data, obtained from CT/XA/MR/US 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 Cerebral Aneurysm 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.

The MR Coronary Tracking application is intended to assist physicians with performing coronary artery analysis for MR heart images which are intended for the qualitative and quantitative analysis of coronary arteries.

The SUREVolume Synthesis application is intended to load volume images acquired by whole-body X-ray CT scanners, X-ray angiography systems, and MRI systems and displays fusion images.

The Angio Viewer application displays image data acquired using an X-ray angiography system. It supports cine display, subtraction, and distance measurement.

The US Cardiac Fusion application enables fusion display of the analysis results obtained using the US 3D Wall Motion Tracking application and the CT Coronary Artery Analysis application.

The Ultrasound Clinical Applications are indicated for the visualization of structures, and dynamic processes with the human body using saved ultrasound DICOM images to provide image information for diagnosis.

SUBSTANTIAL EQUIVALANCE

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. The Ultrasound Clinical Applications Package utilizes the same formulas, algorithms and measurements as found on the predicate device. The porting of this software to the Vitrea Workstation required modifications to the GUI and acquiring images from the Vitrea Image Database. The subject and predicated devices are all post processing applications that are used to aid physicians with performing measurement and analysis of diagnotic images.

A complete comparison table is included in this submission. See below for a brief summary of technological characteristics of the devices:

Primary Predicate:

The primary predicate device is the previous version of the device as cleared by PMN 510(k) K173088 The only changes to primary predicate device are the additions of the software that are described below in the secondary predicate device.

Secondary Predicate:

Item	Ultrasound Clinical Application Package	Aplio i900 Model TUS-AI900
	(Subject Device)	K173090
anatomical region	whole body	whole body
Main feature	Image processing (Visualization of structure and dynamic processes with the human body to provide image information for diagnosis)	Scanning human body using ultrasound probe Image Processing (Visualization of structure and dynamic processes with the human body to provide image information for diagnosis)
Image data format for image processing	DICOM format of ultrasound image data	Original format of ultrasound image data
	- 2D image viewing - 4D / Cardiac 4D image viewing - Stress Echo - Tissue Intensity Analysis - Time Curve Analysis - Automated Cardiac flow Measurement - Cardiac Wall Motion Tracking - Mitral valve analysis	- 2D image viewing - 4D / Cardiac 4D image viewing - Stress Echo - Tissue Intensity Analysis - Time Curve Analysis - Automated Cardiac flow Measurement - Cardiac Wall Motion Tracking - Mitral valve analysis
	- Vitrea based interface is employed	- Ultrasound System interface is employed.

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 IEC62304 and IEC62366.

16. TESTING

Risk analysis and regression testing was 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 sample data sets from the predicate device verification activities (k173090) and verifying that the outputs for both devices were substantially the same.

This device is not subject to Cybersecurity Requirements as it has no access to an outside environment. All images being queued by the VSTP-001A are resident on the host Vitrea platform. The host Vitrea platform conducts all external data transactions and the Cybersecurity documentation is included for the Vitrea.

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.

17. 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 device 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 device.