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K131822

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k)-SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with 21 CFR 807.92, the following summary of the information is provided.

1. **Submitter's Name:**
   Toshiba America Medical Systems, Inc.

2. **Submitter's Address:**
   2441 Michelle Drive
   Tustin, CA 92781-2068

JUL 2 3 2013

3. **Establishment Registration Number:**
   2020563

4. **Contact Person:**
   Charlemagne Chua
   Manager Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   February 25, 2013

6. **Device Proprietary Name:**
   UltraExtend USWS-900A, v2.1
   UltraExtend USWS-900A, v3.1

7. **Common Name:**
   System, Picture Archiving and Communications

8. **Classification:**
   21 CFR §892.2050
   Class II
   Product Code: LLZ

9. **Predicate Devices:**

Product	Marketed by	510(k) Number	Clearance Date
UltraExtend USWS-900A	Toshiba America Medical Systems	K082596	September 23, 2008
UltraExtend FX TUW-U001S v2.02	Toshiba America Medical Systems	K121076	October 9, 2012

10. Reason for Submission:
Modification of the cleared device UltraExtend USWS-900A, K082596

11. Device Description:
UltraExtend USWS-900A v2.1 and v3.1 is a software package that can be installed in a general-purpose personal computer (PC) to enable data acquired from Aplio diagnostic ultrasound systems (Aplio, Aplio XG, Aplio MX, Aplio Artida, Aplio 300, Aplio 400 and Aplio 500), to be loaded onto a PC for image processing with other application software product. UltraExtend USWS-900A v2.1 and v3.1 is a post-processing software that implements functionality and operability equivalent to that of the diagnostic ultrasound system the data was acquired from, providing a seamless image reading environment from examination using the diagnostic ultrasound system to diagnosis using the PC.

12. Indications for Use:
This software is intended for displaying and analyzing ultrasound images for medical diagnosis in cardiac and general examinations.

13. Determination of Substantial Equivalence:
UltraExtend USWS-900A v2.1 and v3.1 functions in a manner similar to and is intended for the same use as the predicate devices UltraExtend, USWS-900A (K082596) and UltraExtend FX (K121076), marketed by Toshiba America Medical Systems.

UltraExtend USWS-900A v2.1 and v3.1 include modifications to the previously cleared device, UltraExtend USWS-900A, which allows data acquired by Aplio 300, Aplio 400 and Aplio 500 Diagnostic Ultrasound Systems (K121422) to be accessible on a PC running UltraExtend USWS-900A v2.1 and v3.1. Additionally, two applications, CHI-Q and TDI-Q, as well as the new feature, 2D wall motion tracking for the images acquired by the Aplio 300, Aplio 400 and Aplio 500 were added. UltraExtend USWS-900A v2.1 runs under Windows XP and v3.1 runs under Windows 7.

UltraExtend USWS-900A v2.1 and v3.1 employs the same fundamental scientific technology as the predicate devices.

A complete comparison of the subject device versus the predicate devices is available in TAB 3 of this submission.

14. Safety:
This device is designed and manufactured under the Quality System Regulations as outlined under 21 CFR§820 and ISO 13485 Standards.

15. Summary of Testing:

a. **Software Documentation**

Risk Analysis, Verification/Validation testing conducted through bench testing, as well as software validation documentation as required by the FDA Guidance Document titled, "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices," are presented in TABS 5 and 7. This documentation demonstrates that the device meets established performance and safety requirements and is therefore deemed safe and effective. Additionally, IEC 62304 processes were implemented in the development of the subject device.

b. Clinical Test

UltraExtend USWS-900A v2.1 and v3.1 did not require clinical studies to support substantial equivalence.

16. Conclusion:

The modifications implemented in the subject device do not change the the intended use of the device. Based upon the safety and effectiveness data/information provided, the clinical performance of UltraExtend USWS-900A v2.1 and v3.1 are deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 23, 2013

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131822
Trade/Device Name: UltraExtend USWS-900A v2.1 and v3.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and IYN
Dated: June 19, 2013
Received: June 20, 2013

Dear Mr. Job:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
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): K131822

Device Name: UltraExtend, USWS-900A, v2.1 and v3.1

Indications for Use:

This software is intended for displaying and analyzing ultrasound images for medical diagnosis in cardiac and general examinations.

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

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) _____K131822_____