DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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AmCad BioMed Corporation
% Chiu S. Lin, Ph.D.
President
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April 26, 2017

Re: K170069
Trade/Device Name: AmCAD-UV
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 24, 2017
Received: March 27, 2017

Dear Dr. Lin:

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.
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)*
K170069

Device Name
AmCAD-UV

Indications for Use *(Describe)*
AmCAD-UV is a software device designed for classifying the ultrasonic color intensity data and allowing users to view classified color-coded signals, namely, primary pulsatile, secondary pulsatile, and unidentified signals of flow Doppler ultrasound images. It is intended as a general-purpose medical image processing tool for vascular pulsatility analysis but must not be used alone for primary diagnostic interpretation.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

1.1 Identification of Submitter:

Submitter:	AmCad BioMed Corporation
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Date prepared:	April 25, 2017

1.2 Identification of Product

Device Trade Name:	AmCAD-UV
Model number:	1.0
Common and Usual Name:	Medical Image Processing and Analysis Software
Device Classification Name:	Picture Archiving and Communications System

Regulation Number: 21 CFR 892.2050
Classification Product Code: LLZ
Classification: Class II
Classification Panel: Radiology Devices
Manufacturer: AmCad BioMed Corporation

1.3 Predicate Device

This subject software medical device is substantially equivalent to the devices listed below:

Primary Predicate Device
Model: QLAB Quantification Software
Manufacturer: Philips Ultrasound, Inc.
510(k) Number: K132165, cleared on August 09, 2013.

In terms of technology, the reference device is listed below.
Model: ClearViewHD
Manufacturer: ClearView Diagnostics Inc.
510(k) Number: K140139, cleared on May 28, 2014

1.4 Device Description

AmCAD-UV (model number 1.0) is a software device designed for classifying the ultrasonic color intensity data and allowing users to view classified color-coded signals, namely, primary pulsatile, secondary pulsatile, and unidentified signals of flow Doppler ultrasound images. The ultrasonic color intensity data here means the flow Doppler ultrasound images (i.e. color and power Doppler ultrasound images) acquired from FDA-cleared ultrasound systems. The device quantifies those color pixels within the quadrilateral scanning area on a sequence of flow Doppler ultrasound images based on their color intensities and groups the color pixels with similar periodic pulsatile waveforms. The image with classified color-coded pulsatile signals will then be generated by the proposed device for users to evaluate the vascular pulsatility,

such as pulsatile flow velocity and flow energy, dependent on the type of flow Doppler ultrasound image analyzed. As a PACS (Picture Archiving and Communication System) software device, AmCAD-UV does not generate new quantities but provide pulsatile information of existing information from flow Doppler ultrasound images. The device is intended as a general-purpose medical image processing tool for vascular pulsatility analysis but must not be used alone for primary diagnostic interpretation. AmCAD-UV provides dual images for viewing original flow Doppler ultrasound images and the image with classified color-coded pulsatile signals. The user can delineate a specific region of interest (ROI) on the image for analysis. The device also provides a trend chart for displaying pulsatile waveforms with summarized statistics. The device can export the quantified values of the classified pulsatile signals in text format and export the sequence of color-coded pulsatile images and the waveform trend chart in Bitmap (*.bmp) and JPEG (*.jpg or *.jpeg) formats.

1.5 Indications for Use

AmCAD-UV is a software device designed for classifying the ultrasonic color intensity data and allowing users to view classified color-coded signals, namely, primary pulsatile, secondary pulsatile, and unidentified signals of flow Doppler ultrasound images. It is intended as a general-purpose medical image processing tool for vascular pulsatility analysis but must not be used alone for primary diagnostic interpretation.

1.6 Comparison with Predicate Devices

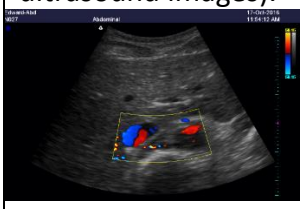
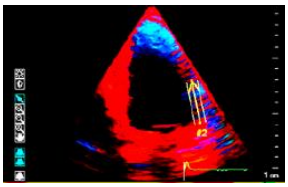
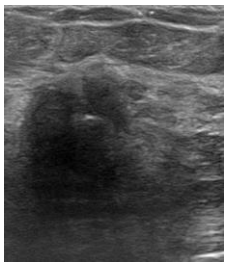
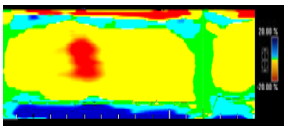
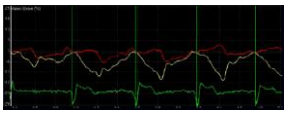
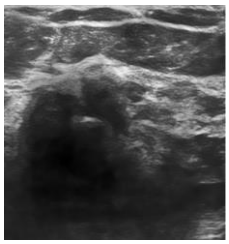
The proposed device is specifically intended for use as a PACS software device for viewing and quantifying the flow Doppler ultrasound image data and is substantially equivalent to the predicate, QLAB Quantification Software, K132165, with the same intended use for viewing and quantifying Doppler ultrasound image data. They both provide statistical analysis of the intensity data or the image content obtained from the ultrasound machine. Both devices are classified as Picture Archiving and Communication System, 21 CFR 892.2050. Minor technological characteristics differences do not raise any new questions of safety and effectiveness. In terms of technology, the reference device is the software used on the ClearViewHD device.

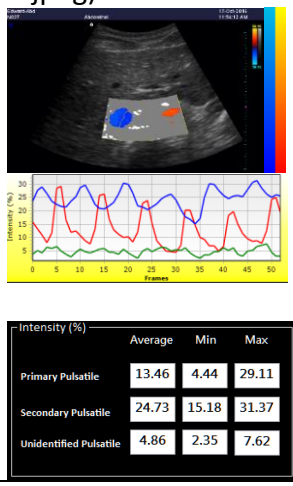
The comparison table 1.6.1 between our device and the predicate devices and reference device is provided below:

Table 1.6.1 **– The substantial equivalence comparison table**

Device	**Proposed Device**	**Primary Predicate Device**	**Reference Device**
	AmCAD-UV	**QLAB Quantification Software**	**ClearViewHD**
Manufacturer	AmCad BioMed Corp.	Philips Ultrasound, Inc.	ClearView Diagnostics Inc.
510(k) Number	K170069	K132165	K140139
Device Common Name	Picture archiving and communications systems	Same	Image Enhancement System
Regulation Number	21 CFR 892.2050 - Class II	Same	Same
Regulation Name	Picture archiving and communications system	Picture archiving and communications system, workstation	Picture archiving and communication system
Product Code	LLZ	Same	Same
Indications for Use/Intended Use	AmCAD-UV is a software device designed for classifying the ultrasonic color intensity data and allowing users to view classified color-coded signals, namely, primary pulsatile, secondary pulsatile, and unidentified signals of flow Doppler ultrasound images. It is intended as a general-purpose medical image processing tool for vascular pulsatility analysis but must not	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products. The software allows users to examine tissue Doppler imaging and provides a tool for drawing regions of interest that measure the myocardial velocity, strain, strain rate, and displacement along those regions in the myocardium	The ClearView Image Enhancement System is intended for use by a qualified technician or diagnostician to reduce speckle noise, enhance contrast and transfer ultrasound images. The software provides a DICOM-compliant ClearViewHD-enhanced image along with the original ultrasound image to assist in image interpretation by the trained physician. ClearViewHD is

Device	Proposed Device	Primary Predicate Device	Reference Device
	AmCAD-UV	**QLAB Quantification Software**	**ClearViewHD**
	be used alone for primary diagnostic interpretation.	(excerpted from QLAB User Manual).	intended for use by a qualified technologist for transfer and enhancement of ultrasound images from a variety of diagnostic systems.
Functional Capability of Image Processing	The device provides dual images for viewing original dynamic f and classified color-coded signals of flow Doppler ultrasound images. The device also provides a trend chart for displaying waveforms of pulsatile intensity changes with summarized statistics. It is intended as a general-purpose medical image processing tool for vascular pulsatility analysis, such as flow velocity and flow energy, over a number of cardiac cycles. AmCAD-UV can export the quantified values of the classified pulsatile signals in text format and export the sequence	The software can display the dynamic intensity information as color-coded image and provide a chart for displaying the intensity changes over time on a waveform, which is able to evaluate the periodic strain fluctuation in myocardial tissue motion over a number of cardiac cycles.	The software generates an enhanced image with reduced speckle noise and improved contrast enhancement for viewing and diagnosing.

Device	Proposed Device	Primary Predicate Device	Reference Device
	AmCAD-UV	QLAB Quantification Software	ClearViewHD
	of color-coded pulsatile images and the waveform trend chart in Bitmap (*.bmp) and JPEG (*.jpg or *.jpeg)formats.		
Software Design/ Example	Based on classification method of ultrasonic color intensity data contained in the dynamic flow Doppler ultrasound images (i.e. color and power Doppler ultrasound images). 	Based on the strain rate method of velocity of myocardial tissue motion contained in the dynamic tissue Doppler images. 	Based on a core noise reduction and contrast enhancement algorithm in gray-scale ultrasound images. 
Output Generated by the Device/ Example	AmCAD-UV allows users to view classified color-coded signals, namely, primary pulsatile, secondary pulsatile, and unidentified signals of flow Doppler ultrasound images and trend chart of intensity changes over time on a waveform. The device exports the quantified values of the classified	The software can display the dynamic intensity information as color-coded image and export the intensity changes over time on a waveform.  	The software can display an image with enhanced contrast and reduced noise. 

Device	Proposed Device	Primary Predicate Device	Reference Device
	AmCAD-UV	**QLAB Quantification Software**	**ClearViewHD**
	pulsatile signals in text format and exports the sequence of color-coded pulsatile images and the waveform trend chart in Bitmap (*.bmp) and JPEG (*.jpg or *.jpeg)formats. 		
Meaning of Color Pixels in the Output	The classified color-coded signals of flow Doppler ultrasound images indicate different intensity values defined by the scale of the color bar.	The color pixels in the virtual trace image indicate different values of myocardial tissue motion information defined by the scale of the color bar.	Not available.
Meaning of Fluctuation in the Waveform	The trends of intensity changes over a sequence of frames is used for evaluation of the periodic fluctuation in vascular pulsatility over a number of	The trends of myocardial information at the user-selected specific points for evaluation of the periodic fluctuation in myocardial tissue	Not available.

Device	Proposed Device	Primary Predicate Device	Reference Device
	AmCAD-UV	**QLAB Quantification Software**	**ClearViewHD**
	cardiac cycles.	motion over a number of cardiac cycles.	
Measurement	Average, maximum, and minimum values for the trends of pulsatile intensity changes.	Mean values for the trends of dynamic intensity information.	Not available.
Type of File to be Processed by the device	Dynamic flow Doppler ultrasound images in DICOM, Bitmap, or JPEG formats (Vendor independent).	Dynamic tissue Doppler image data acquired on Philips Healthcare ultrasound products.	DICOM node that accepts DICOM3.O digital medical files from an ultrasound device or another DICOM source.
Platform/ Operating System	Standard PC, workstation, and on-board FDA-cleared ultrasound systems.	Standard PC, workstation, and on-board Philips' ultrasound systems.	Windows XP or higher, Windows Embedded and DICOM-compliant medical devices.
Clinical Application	Not specified; for general intended use	Same	Same

1.7 Performance Standards

No performance standards for PACS systems or components have been issued under the authority of Section 514.

1.8 General Safety and Effectiveness Concerns

Software development for the AmCAD-UV follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image viewing and quantification device.

The device labeling contains operating instructions for use and necessary warnings and notes to provide the safe and effective use of the AmCAD-UV.

1.9 Summary of Performance Data to Support Substantial Equivalence

AmCad BioMed Corporation has conducted the software verification testing and performance validation testing to evaluate the safety and effectiveness of AmCAD-UV and to validate the performance of the AmCAD-UV for its intended use. The software verification testing, including software unit test, software integration test, and software system test, was performed to ensure that AmCAD-UV meets all functional and specifications for its indications for use. The intended use of the AmCAD-UV was validated in the performance validation testing. The results of performance validation testing (i.e. human validation study) demonstrated that AmCAD-UV can be used to visualize and quantify the primary pulsatile, secondary pulsatile, and unidentified signals of flow Doppler ultrasound images. The images with classified color-coded signals displayed on AmCAD-UV must not be used alone for primary diagnostic interpretation.

1.10 Conclusions

The software development for AmCAD-UV followed documented processes for software design, verification and validation testing, and performance testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for the device. There is no known direct safety or health risk caused by, or related to, the use of the device. The safety and effectiveness of the device has been described in detail in the verification and validation document.

The data presented in this 510(k) application demonstrates that the proposed device, AmCAD-UV, is as safe and effective as the primary predicate device. The intended use of AmCAD-UV is similar to the primary predicate device. The technological differences do not raise any new questions regarding the safety and effectiveness of the device

and the secondary referenced device is listed to reference the similar technological characteristics as that of the proposed device. Thus, AmCAD-UV is substantially equivalent to the predicate device as a software device intended to view and quantifying the ultrasonic image data. Both devices are classified as Picture Archiving and Communication Systems, 21 CFR 892.2050.