**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

AmCad BioMed Corporation
% Chiu S. Lin, Ph.D.
President
Lin & Associates, LLC
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May 30, 2017

Re: K162574
Trade/Device Name: AmCAD-US
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 27, 2017
Received: April 28, 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,

For

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)*
K162574

Device Name
AmCAD-US

Indications for Use *(Describe)*
AmCAD-US is a software device intended to visualize and analyze the statistical distributions of backscattered signals echoed by tissue compositions in the body. The backscattered signals are subject to the RF or Envelope data made available by an FDA-cleared general-purpose ultrasound system. The US-mode images displayed on AmCAD-US 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 |
| Address: | FL.3, NO.167, Fu Hsing N. RD., Taipei 105, Taiwan, R.O.C. |
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| Manufacturer: | AmCad BioMed Corporation |
| | |
| US Agent and Contact: | Chiu S. Lin, Ph.D. |
| | Lin & Associates, LLC |
| Address: | 5614 Johnson Avenue |
| | Bethesda, MD 20817 |
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| E-mail: | cslin@lin-associates.com |
| | |
| Date prepared: | April 27, 2017 |

## 1.2 Identification of Product

| | |
|---|---|
| Device Trade Name: | AmCAD-US |
| 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: Q LAB Quantification Software.
Manufacturer: Philips Ultrasound, Inc.
510(k) Number: K021966, cleared on July 02, 2002.
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In terms of technology, the reference device is listed below.
Model: The software used on Volcano IVUS System.
Manufacturer: Volcano Therapeutics, Inc.
510(k) Number: K042188, cleared on November 10, 2004.

## 1.4 Device Description

AmCAD-US (model number 1.0) is intended to visualize and analyze the statistical distributions of backscattered signals echoed by tissue compositions in the body. AmCAD-US, which uses the proprietary technology and algorithms, is a software package designed to quantify and visualize the backscattered statistics contained in ultrasound image data obtained from an FDA-cleared general purpose ultrasound system. The device provides dual mode images, including conventional B-mode ultrasound image in gray scale and color-mapped US (ultrasound structure) mode image. The US-mode provides a means for viewing and displaying the backscatter statistical values. The device uses parametric model or nonparametric statistics that best describes the distribution curve of the backscattered signals. The parameters

vary by the US method (backscattered statistics) selected. The preferences include options to set the parameters mapped onto the image and US method options applied to the data. The user can also select a specific region of interest (ROI) on the image for quantification analysis. The histogram view of the data provides a different view to accommodate the variation between tissue and tissue states. AmCAD-US has a data export function to record and save the analysis results. Note that the US-mode images displayed on AmCAD-US must not be used alone for primary diagnostic interpretation.

## 1.5 Indications for Use

AmCAD-US is a software device intended to visualize and analyze the statistical distributions of backscattered signals echoed by tissue compositions in the body. The backscattered signals are subject to the RF or Envelope data made available by an FDA-cleared general-purpose ultrasound system. The US-mode images displayed on AmCAD-US 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 ultrasound image data and is substantially equivalent to the predicate, Q LAB Quantification Software, K021966, with the same intended use for viewing and quantifying 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 Volcano IVUS system.

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

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

| **Device** | Proposed Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | AmCAD-US | Q LAB Quantification Software | The software used on Volcano IVUS System |
| **Manufacturer** | AmCad BioMed Corp. | Philips Ultrasound, Inc. | Volcano Therapeutics, Inc. |
| **510(k) Number** | Pending | K021966 | K042188 |
| **Device Common Name** | Picture archiving and communications system | Same | Ultrasonic pulsed echo imaging system and Picture archiving and communications system |
| **Regulation Number** | 21 CFR 892.2050 - Class II | Same | 21 CFR 892.1560 - Class II |
| **Regulation Name** | Picture archiving and communications system | Same | Ultrasonic pulsed echo imaging system (892.1560) |
| **Product Code** | LLZ | LLZ | IYO |
| **Indications for Use/Intended Use** | AmCAD-US is a software device intended to visualize and quantify the statistical distributions of backscattered signals echoed by tissue compositions in the body. The US-mode images displayed on AmCAD-US must not be used alone for primary diagnostic interpretation. The software device provides color-coded | QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products. The Q LAB software provides a means for creating region of interest figures overlaid on the image data displayed by the software. The Q LAB software provides a means of analyzing the content of the image data contained within the ROI figure. | The Volcano Therapeutics, Inc. Volcano IVUS System is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may |

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

| **Device** | Proposed Device<br>AmCAD-US | Primary Predicate Device<br>Q LAB Quantification Software | Reference Device<br>The software used on Volcano IVUS System |
|---|---|---|---|
| | parametric images of backscattered statistics. The color-coded parametric images of the backscattered statstics signals may be useful in assisting the assessment of tissue states of any scanned tissues. The histogram view of the data provides a different view to accommodate the variation in tissue compositions. | The Q LAB software provides a means of presenting the ROI data in an XY graphic format. The Q LAB software provides a means to perform a curve fit operation on a data set generated by the ROI analysis software. The Q LAB software provides a means of exporting the data generated by the plugin modules in a form accessible to the end user. | wish to examine more closely during routine diagnostic ultrasound imaging examinations. |
| **Functional Capability** | AmCAD-US is a software package designed to quantify and visualize the backscatter statistics contained in ultrasound image data obtained from an FDA-cleared general purpose ultrasound system. The device provides dual mode images, including conventional B-mode ultrasound image in gray | QLAB is a software application that is available either as a stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' ultrasound systems. It can be used for the on-line and off-line review and quantification of ultrasound studies. The Region of Interest Quantification (ROI) Q-App is a | The second software program is called IVUSLabVH. This program analyzes each of the slices. These images are visually reviewed and the control points are manually adjusted until they appear in the proper location on the vessel inner and outer borders. Once all the control points have been properly located the software produces a set of |

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

| **Device** | Proposed Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | AmCAD-US | Q LAB Quantification Software | The software used on Volcano IVUS System |
| | scale and color-mapped US (ultrasound structure) mode image. The US-mode provides a means for viewing and displaying the backscatter statistical values. The device uses parametric model or nonparametric statistics that best describes the distribution curve of the backscattered signals. The parameters vary by the US method (backscattered statistics) selected. The preferences include options to set the parameters mapped onto the image and US method options applied to the data. The user can also select a specific region of interest (ROI) on the image for quantification analysis. | tool for analyzing the image pixel content and the time or intensity data in the image. The analysis can display the mean, median, standard deviation, flow index, vascularity index, vascularity flow index, and pixel intensity index for echo, color, and power images. Within the ROI drawn on the image, the mean and median pixel intensity values are calculated for each frame of the sequence in the image file. For each mean intensity value calculated, the standard deviation is calculated. If the exported data contains a single frame, the mean intensity is a single data point. If the exported data contains multiple frames, the mean intensity is graphed as a curve over time with a data point for each frame. | data files called "snaxel" files which define the coordinates of the control points. The black and white IVUS files and the snaxel files are loaded into the IVUSLabVH software which processes the data to produce the five color bit mapped Volcano IVUS image files. The software uses radiofrequency backscatter analysis of IVUS data and produces characterization of different tissue types. |

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

| **Device** | Proposed Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | AmCAD-US | Q LAB Quantification Software | The software used on Volcano IVUS System |
| | AmCAD-US has a data export function to record and save the analysis results. | (derived from QLAB user manual ) | |
| **Input (format)** | RF or envelope data in two dimensional matrix. | Image data of proprietary machine. | Raw data (containing RF signals) of proprietary machine. |
| **Output (format)** | The software can export the data generated by the analysis of the image data in both text and image formats accessible to the users. The text format file contains the statistical value and histogram data. The image format file (.bmp or .jpeg) contains the processed image or data visualization as shown on the user interface. The output information is the backscattered statistics (distribution-related statistics) rendered with | The software can export the data generated by the plugin modules in a form accessible to the end user. The output information includes the descriptive statistics within a user-selected ROI and the specific indices defined by the software.<br>The quantified values are rendered with color codes. The color-coded image is then superimposed on the sonogram. The below exemplar image shows the color-coded overlay image and the trend | The five color bit-mapped Volcano IVUS image files. The software processes the data and produces the five color bit mapped based on the quantified values of backscatter RF analysis and the classified outputs. |

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

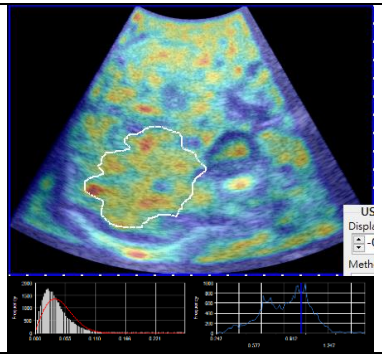
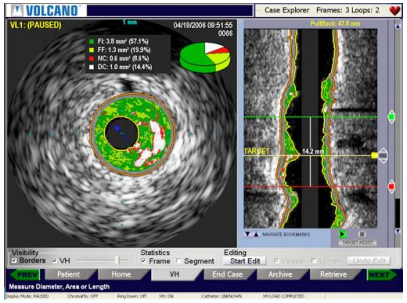
| **Device** | Proposed Device<br>AmCAD-US | Primary Predicate Device<br>Q LAB Quantification Software | Reference Device<br>The software used on Volcano IVUS System |
|---|---|---|---|
| | color codes for visualization and descriptive statistics of ultrasound backscattered data. The below exemplar image shows the color-coded overlay image and the histogram provided by the software. | chart/descriptive statistics provided by the software. | |
| **Example** |  |  |  |
| **Tools provided by the device** | Statistical analysis based on RF data, ROI statistics, distance measurement, data export. | Strain analysis, ROI statistics of image data, distance measurement, data export, etc. | Spectrum analysis of backscattered RF data, ROI statistics, distance measurement, etc. |
| **Software Design** | Based on statistical analysis of ultrasound backscattered | Based on ROI analysis of the image data | Perform radiofrequency (RF) spectral analysis of ultrasound |

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

| **Device** | Proposed Device | Primary Predicate Device | Reference Device |
|---|---|---|---|
| | AmCAD-US | Q LAB Quantification Software | The software used on Volcano IVUS System |
| | signals contained in the image data and statistical analysis in image data | | backscattered signals |
| **Operating System** | Standard PC Operating System | 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-US 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-US.

## 1.9 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

**Verification Tests:**

AmCad BioMed Corporation has conducted the software verification tests, including software unit test, software integration test, and software system test, to evaluate the safety and effectiveness of AmCAD-US. The software verification testing was performed to ensure that AmCAD-US meets all functional and specifications for its indication for use.

**Non-clinical Validation Tests:**

The performance validation tests, including the phantom study, animal study, and human tissue validation study, were performed to validate the performance of the AmCAD-US for its intended use.

- **Phantom Study**

  In the phantom study, AmCAD-US was applied to cell phantoms with different concentrations of one cell type and with different constitutions of mixed cell types. The results of this study demonstrate the utility of the device in analyzing various cell compositions.

- **Animal Study**

  In the animal study, AmCAD-US was applied on 6 rats with liver fibrosis induced by dimethylnitrosamine (DMN) injection. The results of this study demonstrate a strong correlation between the backscattered statistics provided by the device and the dosage of DMN injections. This study also demonstrates the utility of the device in analyzing the variation of the tissue compositions in small animals.

- **Human tissue validation study**

  In the human tissue validation study, two common ultrasound scanning modes, e.g. thyroid and abdomen modes, were applied to demonstrate the utility of proposed device in analyzing backscattered-signal distribution of tissue compositions in the human body. In addition, two different FDA-cleared ultrasound systems were used in this study. The result of this study indicated that the device could be applied to various tissue parts in the human body and can be used with RF/Envelop data provided by various FDA-cleared ultrasound systems.

**Clinical Validation Tests:**

The subject of this 510(k) notification, AmCAD-US, did not require clinical studies to support safety and effectiveness of the software.

## 1.10 Conclusions

The software development for AmCAD-US followed documented processes for software design, software verification testing, and performance 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 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-US, is as safe and effective as the primary predicate device. The intended use of AmCAD-US 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-US is substantially equivalent to the predicate device as a software device intended to view and quantifying the ultrasound image data. Both devices are classified as Picture Archiving and Communication Systems, 21 CFR 892.2050.