December 28, 2018

AmCad BioMed Corporation
% Chiu Lin
President
Lin & Associates, LLC
5614 Johnson Ave
BETHESDA, MD 20817

Re: K180867
Trade/Device Name: AmCAD-UO
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 23, 2018
Received: November 28, 2018

Dear Chiu 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180867

Device Name
AmCAD-UO

Indications for Use *(Describe)*
AmCAD-UO is a PC-based, self-contained, non-invasive image analysis software application for reviewing the pharyngeal/upper airway ultrasonic image acquired from an FDA-cleared ultrasound system. The software is designed to support visualization and quantification of the airway sonographic characteristics. The software also provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern. This analysis provides information for physician's evaluation and monitoring of the airway state.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

5.1 Identification of Submitter:

Submitter:	AmCad BioMed Corporation
Address:	FL.3, NO.167, Fu Hsing N. RD., Taipei 105, Taiwan, R.O.C.
Phone:	886-2-2713-6227
Fax:	886-2-2715-2181
Contact:	Jack Yang
Title:	Vice President
Phone:	886-2-2713-6227 ext.2358
Fax:	886-2-2715-2181
Email:	jack.yang@amcad.com.tw
Manufacturer:	AmCad BioMed Corporation
US Agent and Contact:	Chiu S. Lin, Ph.D.
	Lin & Associates, LLC
Address:	5614 Johnson Avenue
	Bethesda, MD 20817
Phone:	(O) 301-591-3895
E-mail:	cslin@lin-associates.com
Date prepared:	March 28, 2018

FL.3, NO.167, Fu Hsing N. RD., Taipei 105, Taiwan, ROC
Tel: +886-2-27136227 Fax: +886-2-27152181

5.2 Identification of Product

Device Trade Name:	AmCAD-UO
Version number:	1.0
Model number:	UO-0102
Common and Usual Name:	Picture Archiving and Communications System
Device Classification Name:	Picture Archiving and Communications System
Regulation Number:	21 CFR 892.2050
Classification Product Code:	LLZ
Classification:	Class II
Classification Panel:	Radiology
Manufacturer:	AmCad BioMed Corporation

5.3 Predicate Device

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

Primary Predicate Device

Model:	IQQA-Body Imaging Software
Manufacturer:	EDDA Technology, Inc.
510(k) Number:	K141745

.

5.4 Device Description

AmCAD-UO is a PC-based, self-contained, non-invasive image analysis software application for reviewing the pharyngeal/upper airway ultrasonic image acquired from an FDA-cleared ultrasound system. The software is designed to visualization and quantification of the airway sonographic characteristics. The software also provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern. This analysis provides information for physician's evaluation and monitoring of the airway state. The generated information by AmCAD-UO software device must not be used alone for primary diagnostic interpretation.

5.5 Indications for Use

AmCAD-UO is a PC-based, self-contained, non-invasive image analysis software application for reviewing the pharyngeal/upper airway ultrasonic image acquired from an FDA-cleared ultrasound system. The software is designed to support visualization and quantification of the airway sonographic characteristics. The software also provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern. This analysis provides information for physician's evaluation and monitoring of the airway state.

5.6 Comparison with Predicate Devices

The proposed device has different technological characteristics in software design and input images used for analysis, as compared to the predicate device. AmCAD-UO provides the function to review the pharyngeal/upper airway ultrasonic images and analyze the airway characterizes (i.e. size, position and enhancement pattern) based on the statistical pattern recognition and quantification methods. While, the predicate device, IQQA-Body Imaging Software, provides regional volumetric analysis for vascular/ductal/airway structure derived from CT and MR images. Although AmCAD-UO has the above described differences in technological characteristics, as compared to the predicate devices, it does not raise new types of safety or effectiveness questions.

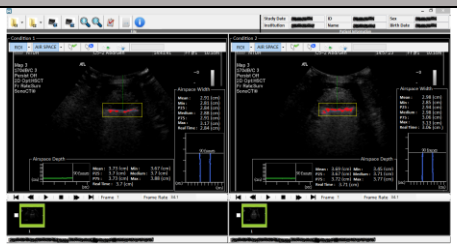
This software, AmCAD-UO is substantially equivalent to the predicate device as described in table 5.6.1.

Table 5.6.1 - The substantial equivalence comparison table

Device	Proposed Device	Predicate Device
	AmCAD-UO	IQQA-Body Imaging Software
Manufacturer	AmCad BioMed Corp.	EDDA Technology, Inc.
510(k) Number	K180867	K141745
Device Common Name	Picture archiving and communications system	Same
Regulation Number	21 CFR 892.2050 - Class II	Same
Regulation Name	Picture archiving and communications system	Same
Product Code	LLZ	Same
Indications for Use	AmCAD-UO is a PC-based, self-contained, non-invasive image analysis software application for reviewing the pharyngeal/upper airway ultrasonic image acquired from an FDA-cleared ultrasound system. The software is designed to support visualization and	IQQA-BodyImaging Software is a PC-based, self-contained, non-invasive image analysis software application for reviewing body imaging studies (including thoracic, abdominal, and pelvic) derived from CT and MR scanners. Combining image viewing, processing and reporting tools, the software is designed to support the visualization,

Device	Proposed Device AmCAD-UO	Predicate Device IQQA-Body Imaging Software
	quantification of the airway sonographic characteristics. The software also provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern. This analysis provides information for physician's evaluation and monitoring of the airway state.	evaluation and reporting of body imaging studies and physician-identified lesions. The software supports a workflow based on automated image registration for viewing and analyzing multiphase and multiple time-point volume datasets. It includes tools for interactive segmentation and labeling of organ segments and vascular/ductal/airway structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path, and allows for regional volumetric analysis of such lesions in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up. The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.
Functional Capability	The software is designed to support visualization and quantification of the airway sonographic characteristics. The software also provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern. This analysis provides information for physician's evaluation and monitoring of the airway state.	Combining image viewing, processing and reporting tools, the software is designed to support the visualization, evaluation and reporting of body imaging studies and physician-identified lesions. The software supports a workflow based on automated image registration for viewing and analyzing multiphase and multiple time-point volume datasets. It includes tools for interactive segmentation and labeling of organ segments and

Device	Proposed Device AmCAD-UO	Predicate Device IQQA-Body Imaging Software
		vascular/ductal/airway structures. The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path, and allows for regional volumetric analysis of such lesions in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up. The software is designed for use by trained professionals, including physicians and technicians. Image source: DICOM.
Input (format)	B-mode dynamic ultrasound image	Digital CT and MR Image data
Output (format)	The software can provide analysis information of the airway in terms of its size, position and enhancement pattern to physicians in evaluating and monitoring the airway state.	The software provides functionalities for manual or interactive segmentation of physician-identified lesions, interactive definition of virtual resection plane and virtual needle path, and allows for regional volumetric analysis of physician-identified lesions or organ segments and vascular/ductal/airway structures in terms of size, position, margin, and enhancement pattern, providing information for physician's evaluation and treatment planning, monitoring, and follow-up.

Device	Proposed Device	Predicate Device
	AmCAD-UO	IQQA-Body Imaging Software
Example		
Tools provided by the device	The software also provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern with ultrasound images.	The software also provides tools for interactive segmentation and labeling of organ segments and vascular/ductal/airway structures with CT/MR images.
Software Design	Based on Statistical Pattern Recognition and Quantification method of airway.	Based on regional volumetric analysis of such lesions and organs
Operating System	Standard PC operating system	Same

5.7 Performance Standards

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

5.8 General Safety and Effectiveness Concerns

Software development for the AmCAD-UO 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-UO.

5.9 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-UO and to validate the performance of the AmCAD-UO 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-UO meets all functional and specifications for its indication for use. Phantom images were created to verify the accuracy of the region of interest (ROI) identification and the quantification of the airspace characteristics by the software under allowable ranges of parameter settings. AmCAD-UO performance was also validated through clinical assessment with a very limited sample size of human subjects. Comparison was performed against MRI measurements. It was found that the two measurement methods exhibit a significant correlation, i.e., a larger airway width measured in one method should be also observed larger in the other method. However, we are not able to conclude from the study, due to the small sample size and the systematic difference between the two imaging modalities, that the two measurement methods fully agree with each other.

FL.3, NO.167, Fu Hsing N. RD., Taipei 105, Taiwan, ROC
Tel: +886-2-27136227 Fax: +886-2-27152181

AmCAD-UO provides tools for manual or interactive selection of Region of Interest to allow for analysis of the airway in terms of its size, position and enhancement pattern. The results demonstrated that AmCAD-UO can be used to visualize and quantify the airway in terms of its size, position and enhancement pattern. The analyzed images displayed on AmCAD-UO must not be used alone for primary diagnostic interpretation.

5.10 Conclusions

The software development for AmCAD-UO followed documented processes for software design, verification testing, 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 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-UO, is as safe and effective as the predicate device. The intended use of AmCAD-UO is similar to the predicate device. The technological differences do not raise any new questions regarding the safety and effectiveness of the device. Thus, AmCAD-UO is substantially equivalent to the predicate device as a software device intended to view and analyze airway structures of ultrasound image. Both devices are classified as Picture Archiving and Communication Systems, 21 CFR 892.2050.