AmCad BioMed Corporation
% Nathan Liu
Product Specialist
FL.5-2, NO.167, Fu Hsing N. RD.
Taipei 105
TAIWAN

September 8, 2021

Re: K203555
Trade/Device Name: AmCAD-UT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: July 30, 2021
Received: August 2, 2021

Dear Nathan Liu:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203555

Device Name
AmCAD-UT

Indications for Use *(Describe)*
AmCAD-UT is a Windows-based computer-aided detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images, acquired from FDA-cleared ultrasound systems. The region of interest (ROI) of a user-selected thyroid nodule is defined by users or suggested by an AI contouring algorithm. After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on ultrasound images of discrete thyroid nodules larger than 1cm, for which a biopsy recommendation is required.

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

K203555

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.5-2, NO.167, Fu Hsing N. RD., Taipei 105, Taiwan, R.O.C.
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Manufacturer:	AmCad BioMed Corporation
Date prepared:	November 27, 2020
Date revised:	September 02, 2021

5.2 Identification of Product

Submission Number:	K203555
Device Trade Name:	AmCAD-UT
Device Classification Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR 892.2050
Classification Product Code:	QIH
Classification Panel:	Radiology
Classification:	Class II
Manufacturer:	AmCad BioMed Corporation

5.3 Predicate Device

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

Model: AmCAD-UT Detection 2.2
Manufacturer: AmCad BioMed Corporation
510(k) Number: K180006

5.4 Device Description

AmCAD-UT is a Windows-based computer-assisted detection (CADe) software application device designed to assist medical professionals in analyzing thyroid ultrasound images with the region of interest (ROI) of a selected nodule defined by users or suggested by an AI algorithm after the user specifies the location of the nodule.

After the initial review of thyroid ultrasound images by the physician, he/she can use AmCAD-UT to analyze thyroid images for further interpretation. Once the ROI is confirmed, the physician may process the image for detection and quantification of sonographic characteristics (i.e., hyperechoic foci, echogenicity, texture, margin, orientation and anechoic areas) by AmCAD-UT. The device provides more detailed information with quantification and visualization of the sonographic characteristics of thyroid nodule that may assist physician in his/her complete interpretation.

The software application automatically generates reports given the user preference inputs (e.g., the nodule size, nodule location and shape, and the presence or absence of the sonographic characteristics) annotated during the image analysis process. A report form has been designed by AmCad to be consistent with the conventional clinical thyroid report form. An output of the report may be viewed and sent to paper printers or saved on the standalone PC or review station as PDF file.

5.5 Indications for Use

AmCAD-UT is a Windows-based computer-aided detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images, acquired from FDA-cleared ultrasound systems. The region of interest (ROI) of a user-selected thyroid nodule is defined by users or suggested by an AI contouring algorithm. After the initial review of the ultrasound images by the physicians, the device further

provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on ultrasound images of discrete thyroid nodules larger than 1cm, for which a biopsy recommendation is required.

5.6 Comparison with Predicate Devices

AmCAD-UT is a computer-assisted detection (CADe) device which provides viewing and post-acquisition image processing and analysis of thyroid ultrasound images with regions of interest (ROI) and automatically generates reports from user inputs annotated during the image analysis process. This software medical device is substantially equivalent to the predicate device listed below:

Model: AmCAD-UT® Detection, Version 2.2
Manufacturer: AmCad BioMed Corporation
510(k) Number: K180006
The comparison as described in the following table:

	AmCAD-UT	**AmCAD-UT® Detection 2.2**
Manufacturer	AmCad BioMed Corp.	AmCad BioMed Corp.
510(k) Number	K203555	K180006
Regulation Number	21 CFR 892.2050 - Class II	21 CFR 892.2050 - Class II
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System
Product Code	QIH	LLZ
Intended Use	AmCAD-UT is intended to assist the medical professionals in analyzing thyroid ultrasound images by quantification and visualization of sonographic characteristics of thyroid nodules.	AmCAD-UT® Detection 2.2 is intended to assist the medical professionals in analyzing thyroid ultrasound images of user-selected regions of interest (ROI). After the initial review of the ultrasound images by the physicians, the device further provides detailed information with

	AmCAD-UT	AmCAD-UT® Detection 2.2
		quantification and visualization of sonographic characteristics of thyroid nodules.
Indications for Use	AmCAD-UT is a Windows-based computer-aided detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images, acquired from FDA-cleared ultrasound systems. The region of interest (ROI) of a user-selected thyroid nodule is defined by users or suggested by an AI contouring algorithm. After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on ultrasound images of discrete thyroid nodules larger than 1cm, for which a biopsy recommendation is required.	AmCAD-UT® Detection 2.2 is a Windows-based computer-aided detection (CADe) device intended to assist the medical professionals in analyzing thyroid ultrasound images, acquired from FDA-cleared ultrasound systems, with user-selected regions of interest (ROI). After the initial review of the ultrasound images by the physicians, the device further provides detailed information with quantification and visualization of sonographic characteristics of thyroid nodules. The device is intended for use on ultrasound images of discrete thyroid nodules larger than 1cm, for which a biopsy recommendation is required.
Functional Capability of Image Processing	AmCAD-UT analyzes the user-defined or AI-suggested regions of interest (ROI) of a user-selected thyroid nodule for detection and quantification of sonographic characteristics (hyperechoic	AmCAD-UT® Detection 2.2 analyzes the user-selected regions of interest (ROI) of thyroid ultrasound image for the detection and quantification of sonographic characteristics (hyperechoic

	AmCAD-UT	AmCAD-UT® Detection 2.2
	foci, echogenicity, texture, margin, orientation and anechoic areas). The device further provides detailed information with visualization of sonographic characteristics of thyroid nodules.	foci, echogenicity, texture, margin, orientation and anechoic areas). The device further provides detailed information with visualization of sonographic characteristics of thyroid nodules.
Reading Paradigm	AmCAD-UT is to provide quantification and visualization of sonographic characteristics after physicians' initial review of the images.	AmCAD-UT® Detection 2.2 is to provide quantification and visualization of sonographic characteristics after physicians' initial review of the images.
Output Generated by the CAD Device	The image can be annotated with the detected sonographic characteristics and be recorded by the device. The software also automatically generates reports given the user preference inputs in the analysis process.	The image can be annotated with the detected sonographic characteristics and be recorded by the device. The software also automatically generates reports given the user preference inputs in the analysis process.
Type of Film to be Processed by the CAD Device	Digital ultrasound image	Digital ultrasound image
Software Design	Based on AI, Statistical Pattern Recognition and Quantification method	Based on Statistical Pattern Recognition and Quantification method
Ground Truth Establishment	The ground truth to be established for performance studies of the device is the ROI labeled by a panel of specialists.	The ground truth to be established for performance studies of the device includes the ROI, the presence of each sonographic characteristic, and the surgical pathology examination result.
Platform	Window-based	Window-based
Operating System	Standard PC or review station	Standard PC or review station
Clinical Application	Thyroid cancers	Thyroid cancers

	AmCAD-UT	AmCAD-UT® Detection 2.2
Image Type	Ultrasound Image	Ultrasound Image
Image Format	DICOM3.0, Bitmap, JPEG	DICOM3.0, Bitmap, JPEG
ROI Quantification	Yes	Yes
Automatically Generating Report	Yes	Yes
Report Storage	Paper printers, Local disk	Paper printers, Local disk
Performance Testing Data to Support SE Determination	Results from standalone performance testing of the AI suggested ROI's of user-selected nodules	Results from standalone performance testing and clinical performance testing (MRMC study)

AmCAD-UT is substantially equivalent to AmCAD-UT® Detection 2.2 that provides display and post-acquisition image analysis of ultrasound images assisting the physician in analyzing the ultrasound images of thyroid nodules. The standalone performance assessment results of AmCAD-UT are shown substantially equivalent to AmCAD-UT® Detection 2.2. The minor technological difference, i.e., the addition of the AI-suggested ROI of a user-selected nodule, do not raise any new questions of safety and effectiveness. Thus, AmCAD-UT is substantially equivalent to the predicate device as a Computer-Assisted Detection (CADe) device intended to assist the physicians in clinical practice.

5.7 Performance Standards

No applicable FDA performance standards have been issued under the authority of Section 514.

5.8 Software

Software development for the AmCAD-UT 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.

5.9 Summary of Performance Data to Support Substantial Equivalence

AmCad BioMed Corporation has conducted standalone performance studies to validate and assess the performance of the AmCAD-UT for its added function of AI-suggested ROI contouring. The standalone studies evaluated the performance of the contours suggested by the AI algorithm of user-selected nodules on images acquired from FDA-cleared ultrasound systems and showed that the device was effective in determining the contour of thyroid nodules.

5.10 Conclusions

AmCAD-UT, being a computer assisted detection (CADe) software device, has the same intended use as the predicate device. The suggested ROI of a user-selected nodule is added in this proposed device and the performance data demonstrates that it performs effectively and the device is as safe and effective as the predicate device. AmCAD-UT is, therefore, substantially equivalent to the predicate devices as the new function of the device assists the medical professionals in identifying the contours of thyroid nodules without interfering with the analysis functions of the device.