PLUM Medical Solutions GmbH
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

March 23, 2018

Re: K173241
Trade/Device Name: MED-TAB
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2018
Received: March 1, 2018

Dear Mr. Alletto:

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.

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.

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,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173241

Device Name
MED-TAB

Indications for Use *(Describe)*
MED-TAB, is a computer hardware/software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.

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 being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

March 21, 2018

Submitter's Information: 21 CFR 807.92(a)(1)

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: MED-TAB

Common Name: Picture Archiving Communications System

Classification Name: system, image processing, radiological
Product code: LLZ

Classification Name: display, diagnostic radiology
Product Code: PGY

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological[22]
510(k) Number	K062488
Device Name	IQ-SYSTEM PACS SYSTEM
Applicant	IMAGE INFORMATION SYSTEMS, LTD.
Applicant Contact	Carl Alletto
Regulation Number	892.2050
Classification Product Code	LLZ
Decision Date	09/19/2006
Decision	substantially equivalent (SESE)
Regulation Medical Specialty	Radiology
summary	summary
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

Device Description: 21 CFR 807 92(a)(4)

MED-TAB is a 13.3" color LCD monitor including a built-in tablet computer for viewing and analyzing of medical images (except those of mammography) from a picture archiving and communication system (PACS). The color panel employs in-plane switching (IPS) technology allowing wide viewing angles.

MED-TAB has one regular display mode to visualize non-medical images, and one DICOM factory calibrated display mode to display medical images according to DICOM regulations.

The MED-TAB has been calibrated to comply with DICOM Part 14 at the factory. With built-in brightness stabilization circuit, USB adjustment tool and ambient light sensor, stable brightness and persistent calibration can be guaranteed. The MED-TAB can support both landscape and portrait mode. The anti-reflection coated protective screen can prevent display damage under heavy operating conditions. The tablet-PC is designed in conformity with IEC60601-1, and IEC60601-1-2 standards.

Off-the-shelf (OTS) software is used for the mobile viewer application. It supports DICOM image files as well as other common image formats and PDF files.

The major image viewing functions device are:

- Receive DICOM data per pre-defined communication setup by Picture Archiving and Communication System (PACS)
- Overview of available patients, including a search function (name, birth date, imaging modality)
- Selection of to be reviewed DICOM data to download an entire set of data (multiple patients, multiple studies or multiple series)
- Visualization of the DICOM data in a well-established way of DICOM viewing (analogous standard tools for medical image viewing)
- Assessment of DICOM data by means of standard navigation tools (level window, panning, zooming, etc.)
- Take pictures for wound documentation and send them as a DICOM file to your PACS including all necessary meta information
- Calibration routine to adjust the display of grey values on a device - DICOM Greyscale Standard Display Function
- Create simple textual reports and store them as a DICOM file
- Load and create level window presets
- Manual measurement of structures of interest on 2D slices including angular and length measurements as well as statistical computations in a region of interest
- Adding text annotations to images
- Multiplanar reconstruction for CT datasets (MPR)
- Thick slices by means of maximum intensity projection for up to 11 slices (MIP)
- Browse PACS by DICOM Query (C-FIND)
- Request data by DICOM Retrieve (C-MOVE)
- Encryption and compression of data stored/transmitted
- Sending messages / images / key images to colleagues, which are shown in a contact list

MED-TAB does not contact the patient, nor does it control any life sustaining devices. The software does not provide any diagnostic assistance to the physician. Any diagnostic determination or treatment is solely determined by a physician and not the software. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

Indications for Use: 21 CFR 807 92(a)(5)

MED-TAB, is a computer hardware/software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems. Images and data can be stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations.

Mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with clinical application.

Technological Characteristics: 21 CFR 807 92(a)(6)

MED-TAB, does not contact the patient, nor does it control any life sustaining devices.

A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed. The general features and functions of the device are as follows:

Item description	Predicate device: iQ Systems PACS K062488	New Device: MED-TAB
Computer platform (minimum requirements)	Pentium IV CPU > 1.5 GHz or comparable AMD processor. minimum 20 GB hard disk, depending on the volume of the data to be saved temporary, and with DMA33 ability 3D graphics card nVidia GeForce ≥ 5600 or higher, ATI ≥ Radeon 9600, with at least 64 MB of RAM analogous color monitor, resolution of 1024 × 768 CD-R drive to install the program from CD-ROM	• CPU: Quad core Intel-compatible x86 64bit Processor • HDD: 32GB
System RAM	≥ 1 GB main memory, depending on the 3D datasets	• RAM: 1GB
Operation System	Microsoft Windows 2000, or Windows XP	• Android 4.4.4 • Android 6.0 • Android 7.0 • iOS 10.0.2 • Windows 10 x64 • Windows 7 x64
Image Acquisition	Frame grabber or Vidar Diagnostic Pro film scanner system or similar	There is no frame grabber in the Subject Device.
Transmission resolution (max.)	1280 x 1024, 8-bit display or 12 bits deep	1920 x 1080 Pixel, 11 Bit internally, 8-bit display
Image Compression:	Compression mode: none, Lossless (Differential Pulse Code Modulation), or Lossy (Wavelet/JPEG)	No compression or Lossless only.
Modality Support	DICOM and non-DICOM images from Computer Radiography, CT, MRI, Nuclear Medicine, Ultra Sound, Secondary Capture Secondary Capture	Same as predicate
Networking Communications Protocol	DICOM 3.0	Same as predicate
Standard Interfaces	SCSI or Modem. Network connection with at least 10 MBit/s	Same as predicate
Image Storage	On board hard disk size & compression dependent. Can store to Short or Long-Term Archives	Same as predicate

Item description	Predicate device: iQ Systems PACS K062488	New Device: MED-TAB
Image Interaction Features	• 'Level Window' • 'Thickness' • 'Panning'	Same as predicate
Image Tools	• 'DICOM Cine' • 'Zoom': • 'Create report'	Same as predicate
Image Annotations	• 'Measurement' • 'Note' • 'Arrow' • 'Region of interest' • 'Angle' • 'Remote angle': • 'Length ratio' • 'Save key image (to PACS) • 'List of annotations'	Same as predicate
Image Search	• Overview about all available patients, including a search function (name, birth date, imaging modality)	Same as predicate
Multiplanar reconstruction for CT datasets (MPR	Yes	Yes
Sending messages / images / key images to colleagues, which are shown in a contact list	Yes	Yes

Testing

The complete system configuration has been tested at the factory and the device has passed all in-house pre-determined testing criteria without significant failures. The data presented in the submission demonstrates that MED-TAB performs as required according to the functional requirements specified in the Software Requirements Specification and the User Manual with no errors that had an impact on safety or efficacy.

Conclusion: 21 CFR 807 92(b)(1)

The 510 (k) Pre-Market Notification for MED-TAB contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. MED-TAB has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the “Level of Concern for potential hazards has been classified as “Moderate”.